

Changes have been made to this public summary document (PSD). Details of the corrigendum are recorded in Section 8. An addendum to this PSD has been included at the end of the document.

**6.01 ADALIMUMAB,
Injection 20 mg in 0.2 mL pre-filled syringe,
Injection 40 mg in 0.4 mL pre-filled syringe,
Injection 40 mg in 0.4 mL pre-filled pen,
Injection 80 mg in 0.8 mL pre-filled syringe,
Injection 80 mg in 0.8 mL pre-filled pen,
Humira[®],
AbbVie Pty Ltd.**

1 Purpose of submission

- 1.1 The Category 2 submission requested a General Schedule Authority Required (STREAMLINED) listing for adalimumab (Humira[®]) for the treatment of immune-mediated inflammatory disease (IMID) in paediatric patients.
- 1.2 The submission requested that adalimumab be PBS-listed as an indication-agnostic listing to allow patients with the greatest risk of permanent disability and/or psychological distress to receive treatment with adalimumab.

2 Background

- 2.1 The submission claimed that children in Australia with IMIDs are currently disadvantaged in terms of access to treatment compared to other countries such as the United States, Canada, United Kingdom, Germany and New Zealand. The submission stated that extending the PBS listing of adalimumab to allow access by paediatric patients with IMIDs would align with treatment guidelines and international best practice.
- 2.2 The submission claimed many of the current PBS restriction criteria for Humira for paediatric patients are clinically inappropriate, as they:
 - have historically been based on the restriction criteria for adult disease and are not reflective of childhood disease presentations
 - mandate prior failure or intolerance of conventional systemic therapy, even for patients with the most severe disease and those in need of immediate treatment to prevent irreversible outcomes

- do not allow for flexible doses.
- 2.3 The submission stated that early, aggressive treatment of childhood IMIDs may alter the natural course of a child’s disease history. Benefits cited included:
- fewer disruptions in education, less impact on psychosocial development, and reduced need to make life decisions based on their medical condition.
 - health economic benefits of improved access to treatment: fewer medical appointments, hospitalisations and surgeries; reduced permanent disability and the need for allied health services.
 - greater contribution to the economy by parents (and eventually the children) through increased productivity, reduced absenteeism, increased employment and reduced reliance on social welfare.
- 2.4 The submission cited the Inquiry into childhood rheumatic diseases: Interim report by the House of Representatives (HoR) Standing Committee on Health, Aged Care and Sport, and claimed the submission seeks to partly address Recommendation 14:
- ‘The Committee recommends the Australian Government’s Department of Health in partnership with the Pharmaceutical Benefits Advisory Committee, experts, patient groups and sponsoring companies conduct an urgent review into:
- access to treatments for juvenile arthritis including access to drugs not currently available in Australia, and
 - limitations on access to existing listed medications that prevent patients receiving the most effective medications.’
- 2.5 The submission also stated that extending the PBS listing for adalimumab aligns with the Standing Committee on Health, Aged Care and Sport’s recommendation to repurpose older medicines in Australia, as it will provide paediatric populations with a high unmet need with a medicine that has already been approved in other jurisdictions, used for less common medical conditions, is already being used off-label, and is likely to be less commercially profitable.

Registration status

- 2.6 Humira is Therapeutic Goods Administration (TGA) registered for the following indications in children and adolescents:
- Juvenile idiopathic arthritis: polyarticular juvenile idiopathic arthritis in patients ≥ 2 years of age who have had inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs); enthesitis-related arthritis in children who have had an inadequate response to, or are intolerant to, conventional therapy

- Moderate to severe Crohn disease in children ≥ 6 years (and adults) in patients who have had an inadequate response to conventional therapies, or who have lost response to or are intolerant to infliximab
 - Psoriasis: severe chronic plaque psoriasis in children ≥ 4 years and adolescents who have had an inadequate response to or are inappropriate candidates for topical therapy or phototherapy; moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
 - Active moderate to severe hidradenitis suppurativa (HS) in adults and adolescents ≥ 12 years with an inadequate response to conventional systemic HS therapy.
- 2.7 In addition, Humira is TGA registered for the following indications in adults:
- Moderate to severely active rheumatoid arthritis
 - Psoriatic arthritis
 - Ulcerative colitis
 - Non-infectious intermediate, posterior and pan-uveitis.
- 2.8 Humira is TGA-registered for active ankylosing spondylitis with no age specified.
- 2.9 The Economics Sub Committee (ESC) noted that the requested listing will include paediatric indications that adalimumab is TGA-registered for and will also allow use in indications not currently TGA-registered.

Previous PBAC consideration

- 2.10 Humira was first listed on the PBS on 1 May 2004 for the treatment of severely active rheumatoid arthritis in adults, following a recommendation for listing by the PBAC at its December 2003 meeting.
- 2.11 The PBAC first considered the listing of Humira for a paediatric indication at its March 2010 meeting. At this meeting, the PBAC recommended listing Humira (20 mg/0.4 mL and 40 mg/0.8 mL pre-filled syringe) for the treatment of severe active polyarticular course juvenile idiopathic arthritis (Section 12, adalimumab, PSD, March 2010 PBAC meeting).
- 2.12 At its November 2014 meeting the PBAC recommended extending the listing of Humira (20 mg/0.4 mL and 40 mg/0.8 mL) to include listing for the treatment of severe refractory Crohn disease in paediatric patients aged 6-17 years (paragraph 7.1, adalimumab, PSD, November 2014 PBAC meeting).
- 2.13 At its March 2016 meeting the PBAC recommended listing Humira (40 mg/0.8 mL) for the treatment of moderate to severe ulcerative colitis (paragraph 7.1, adalimumab, PSD, March 2016 PBAC meeting). The March 2016 submission agreed to broaden the restriction to include paediatric patients as well as adult patients as suggested by the

PBAC at its July 2015 and November 2015 considerations. However, the submission maintained its proposed restriction limiting to adult patients was consistent with the TGA registered indication (Table 1, adalimumab, PSD, March 2016 PBAC meeting).

- 2.14 At its December 2016 meeting, the PBAC recommended listing Humira (40 mg/0.8 mL) for the treatment of moderate-to-severe hidradenitis suppurativa (adalimumab, PSD, November 2016 PBAC meeting with December 2016 Addendum). The recommended listing had no restrictions on patient age.
- 2.15 The sponsor made a resubmission to request a General Schedule Authority Required (Telephone/Online) listing for adalimumab for the treatment of patients with vision-threatening non-infectious uveitis, which was also considered by the PBAC at its March 2024 meeting. The submission noted there was partial overlap in patient populations between the two submissions.

Current PBS listings

- 2.16 Humira is currently PBS-listed for the following indications for paediatric patients:
- Severe active juvenile idiopathic arthritis (Population criteria: patient must be under 18 years of age): Humira 20 mg/0.2 mL, 40 mg/0.4 mL pre-filled syringe; 40 mg/0.4 mL pre-filled pen (Authority Required (Telephone/Online) for initial/first continuing treatment; Authority Required (STREAMLINED) for continuing treatment).
 - Severe Crohn disease (Population criteria: patient must be aged 6-17 years inclusive): Humira 20 mg/0.2 mL, 40 mg/0.4 mL, 80 mg/0.8 mL pre-filled syringe; 40 mg/0.4 mL, 80 mg/0.8 mL pre-filled pen (Authority Required (written)). The 80 mg/0.8 mL dose forms are not subsidised for continuing treatment.
 - Moderate to severe ulcerative colitis (Population criteria: patient must be 6 years of age or older): Humira 20 mg/0.2 mL, 40 mg/0.4 mL, 80 mg/0.8 mL pre-filled syringe; 40 mg/0.4 mL, 80 mg/0.8 mL pre-filled pen (Authority Required (written)) for initial treatment, Authority Required (Telephone/Online) for continuing treatment where relevant (the 80 mg/0.8 mL dose forms are not subsidised for continuing treatment)).
- 2.17 In addition, Humira is currently PBS-listed for the following conditions with no age criteria specified:
- Complex refractory Fistulising Crohn disease: Humira 40 mg/0.4 mL and 80 mg/0.8 mL pre-filled syringe and pre-filled pen (Authority Required (written)). The 80 mg/0.8 mL dose forms are not subsidised for continuing treatment.

- Hidradenitis suppurativa: Humira 80 mg/0.8 mL pre-filled syringe; 40 mg/0.4 mL, 80 mg/0.8 mL pre-filled pen (Authority Required (written) for initial treatment, Authority Required (Telephone/Online) for continuing treatment).

For more detail on PBAC's view, see section 7 PBAC outcome.

3 Requested listing

3.1 Suggested additions proposed by the Secretariat are in italics and deletions are crossed out with strikethrough.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	2	4	4	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	2	4	4	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	NEW	3	3	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe	NEW	3	3	0	Humira
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [new]					
Administrative Advice: <i>No increase in the maximum quantity or number of units may be authorised.</i>					
Administrative Advice: <i>No increase in the maximum number of repeats may be authorised.</i>					
Episodicity: [blank]					
Severity: Disease severity considered sufficient to cause substantial detriment to patient's immediate or future health or quality of life					
Condition: Immune-mediated inflammatory diseases					
Indication: Immune-mediated inflammatory diseases					
Treatment Phase: Initial treatment					
Clinical criteria:					
<i>Patient must have a confirmed diagnosis of an immune-mediated inflammatory disease which, in the opinion of the treating specialist, would derive clinical benefit from treatment with adalimumab;</i>					
AND					
Clinical criteria:					
<i>Patient must have, at the time of application, disease severity considered sufficient to cause substantial detriment to patient's immediate or future health or quality of life, according to at least 2 measures of disease severity or quality of life impact (at least 1 must be an objective measure) appropriate to the patient's condition and age;</i>					
AND					
Clinical criteria:					
<i>Patient must not have experienced an inadequate response to this therapy;</i>					

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Committee In Confidence*

AND
Clinical criteria:
Patient must not receive more than 16 weeks of treatment <i>with this biological medicine</i> under this restriction.
Treatment criteria:
Must be treated by a specialist paediatric clinician or specialist clinician with experience in treating the disease.
Population criteria:
Patient must be under 18 years of age.
Prescribing Instructions:
The assessment of disease severity and quality of life impact must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	2	4	6	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	2	4	6	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	2	4	6	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	NEW	1	2	6	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe	NEW	1	2	6	Humira
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [new]					
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
Administrative Advice: No increase in the maximum number of repeats may be authorised.					
Episodicity: [blank]					
Severity: Disease severity considered sufficient to cause substantial detriment to patient's immediate or future health or quality of life					
Condition: Immune-mediated inflammatory diseases					
Indication: Immune-mediated inflammatory diseases					
Treatment Phase: Continuing treatment					
Clinical criteria:					
Patient must have a confirmed diagnosis of an immune-mediated inflammatory disease which, in the opinion of the treating specialist, would derive clinical benefit from treatment with adalimumab;					
AND					
Clinical criteria:					
Patient must have previously received PBS-subsidised treatment with this drug for this condition;					
AND					
Clinical criteria:					
Patient must have demonstrated an adequate clinical response to treatment according to the objective and/or subjective measures of disease recorded at baseline;					
AND					

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Clinical criteria:
Patient must not receive more than 28 weeks of treatment <i>per continuing treatment course authorised</i> under this restriction.
Treatment criteria:
Must be treated by a specialist paediatric clinician or specialist clinician with experience in treating the disease.
Population criteria:
Patient must be under 18 years of age.
Prescribing Instructions: An adequate response to treatment is defined as: A clinically meaningful improvement in the measures of disease severity and/or quality of life impact that were used to establish baseline severity The assessment of adequate response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.
Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new]
Indication: Immune-mediated inflammatory diseases
Treatment Phase: Continuing adult with paediatric history
Clinical criteria:
<i>Patient must have a confirmed diagnosis of an immune-mediated inflammatory disease which, in the opinion of the treating specialist, would derive clinical benefit from treatment with adalimumab;</i>
AND
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition;
AND
Clinical criteria:
Patient must have demonstrated an adequate clinical response to treatment according to the objective and/or subjective measures of disease recorded at baseline;
AND
Clinical criteria:
Patient must not receive more than 28 weeks of treatment under this restriction.
Treatment criteria:
Must be treated by a specialist paediatric clinician or specialist clinician with experience in treating the disease.
Population criteria:
Patient must be <i>at least over</i> 18 years of age.
Prescribing Instructions: An adequate response to treatment is defined as: A clinically meaningful improvement in the measures of disease severity and/or quality of life impact that were used to establish baseline severity The assessment of adequate response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.
Category / Program: GENERAL – General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new]
Indication: Immune-mediated inflammatory diseases
Treatment Phase: Initial PBS-subsidised treatment in a patient who has previously received non-PBS subsidised therapy with this drug (grandfather)

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Clinical criteria:
Patient must have previously received non-PBS subsidised treatment with this drug for the <i>this</i> condition prior to 1 [month and year];
AND
Clinical criteria:
Patient must have documented history of an immune-mediated inflammatory disease which, in the opinion of the treating specialist, would derive clinical benefit from treatment with adalimumab;
AND
Clinical criteria:
Patient must have had disease severity considered sufficient to cause substantial detriment to patient's immediate or future health or quality of life, according to at least 2 measures of disease severity or quality of life impact (at least 1 must be an objective measure) appropriate to the patient's condition and age;
AND
Clinical criteria:
<i>Patient must have demonstrated an adequate clinical response to treatment according to the objective and/or subjective measures of disease recorded at baseline;</i>
AND
Clinical criteria:
Patient must not receive more than 28 weeks of treatment <i>with this biological medicine</i> under this restriction.
Treatment criteria:
Must be treated by a specialist paediatric clinician or specialist clinician with experience in treating the disease.
Population criteria:
Patient must be under 18 years of age.
Prescribing Instructions:
The baseline assessment of disease severity and quality of life impact must be documented in the patient's medical records.
Prescribing Instructions:
<i>An adequate response to treatment is defined as: A clinically meaningful improvement in the measures of disease severity and/or quality of life impact that were used to establish baseline severity The assessment of adequate response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</i>
Administrative Advice: <i>Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.</i>
Administrative Advice: <i>This Grandfather restriction will cease to operate 12 months after the date specified in the clinical criteria.</i>

- 3.2 The submission stated that it requested an indication-agnostic listing to allow children who have the greatest risk of permanent disability and/or psychological distress (in the opinion of the treating clinician) to receive immediate treatment with adalimumab. The submission requested the listings be Authority Required (STREAMLINED) to allow for immediate access for patients who should commence treatment without delay and to reduce administrative burden for prescribers.
- 3.3 The current PBS listings for Humira for paediatric populations are Authority Required (written) or Authority Required (Telephone/Online) for initial and first continuing treatment. The Authority requirements for continuing treatment varies depending on the indication (see paragraphs 2.16-2.17).

- 3.4 The submission noted the maximum quantity and number of repeats were calculated based on the highest approved dosing regimen for paediatric patients (patients with Crohn disease who are $\geq 40\text{kg}$ and require a dose of 80 mg adalimumab every 2 weeks). A similar approach was taken for the requested maximum quantity and number of repeats for patients accessing treatment through the proposed Continuing and Grandfather treatment phases. The maximum quantity requested for patients receiving treatment under the 'Continuing adult with paediatric IMID history' restriction was calculated based on adult dosing requirements.
- 3.5 The requested maximum quantities and repeats differ from the maximum quantities and repeats for adalimumab that are currently PBS-listed for certain indications. In many instances the requested maximum quantities and repeats are higher than those currently PBS-listed.
- 3.6 The Pre-Sub Committee Response (PSCR) stated the intent of the requested restriction was that patients who access and subsequently fail to respond to another PBS-subsidised biological treatment for an IMID would not be able to access treatment via this restriction. It stated the sponsor would be open to including a statement in the listing to clarify this and that patients who would qualify under existing listings for adalimumab should not access treatment through the requested listing.
- 3.7 The PSCR noted the proposed clinical criteria in the requested listing was developed in conjunction with clinician working groups, who considered the criteria should be flexible to include both disease severity measures and patient-reported quality of life measures to provide an overall assessment of the patient's disease severity. It considered that rather than specifying particular measures in the restriction criteria, the choice of measure should be left with the treating physician to reflect the variable presentations of IMIDs in children. The PSCR provided the following examples of scores and measures that may be used to assess severity of particular IMIDs:
- Rheumatology conditions: swollen and tender joint counts, overall Physician Global Assessment, Childhood Myositis Assessment Scale (CMAS)/Manual Muscle Testing and a subset of Eight Muscles (MMT8) (Juvenile Dermatomyositis), Patient/Parent Global Assessment of wellbeing.
 - Gastroenterology conditions: Paediatric Crohn's Disease Activity Index (PCDAI), Paediatric Ulcerative Colitis Activity Index (PUCAI), endoscopic scores, magnetic resonance enterography, intestinal ultrasound scores (including bowel wall thickness), faecal calprotectin.
 - Dermatology conditions: Psoriasis Activity and Severity Index (PASI), Hidradenitis Suppurativa Clinical Response (HiSCR), Severity-of-Illness Score for Toxic Epidermal Necrolysis (SCORTEN) (Steven Johnson Syndrome/Toxic Epidermal Necrolysis), Children's Dermatology Life Quality Index (CDLQI).

The ESC noted the extensive consultation undertaken with various clinical groups in the preparation of this submission.

- 3.8 The PSCR acknowledged the requested maximum quantity and repeats differ from the maximum quantities and repeats for current PBS-listings for adalimumab. However, it argued that the requested 28 weeks maximum treatment duration better aligns with patients' usual scheduling of appointments with their specialist (i.e. every 3 to 6 months).

For more detail on PBAC's view, see section 7 PBAC outcome.

4 Population and disease

- 4.1 Adalimumab is a recombinant human immunoglobulin monoclonal antibody. Adalimumab binds to tumour necrosis factor (TNF) and neutralises the biological function of TNF by blocking its interaction with the p55 and p75 cell surface TNF receptors. Elevated levels of TNF are found in the synovial fluid of rheumatoid arthritis, including juvenile idiopathic arthritis, psoriatic arthritis and ankylosing spondylitis patients and play an important role in both the pathologic inflammation and the joint destruction that are hallmarks of these diseases. Increased levels of TNF are also found in psoriasis plaques, which contribute to the inflammatory response, the proliferation and decreased maturation of keratinocytes and to the associated vascular damages that are characteristic of the disease (Humira Product Information).
- 4.2 The submission requested an indication-agnostic PBS-listing for the treatment of IMiDs in paediatric patients, to cover all possible IMiDs in which adalimumab is expected to be used.
- 4.3 The submission proposed the population be limited to patients who, in the opinion of the treating clinician, may derive clinical benefit from treatment with adalimumab, and to patients whose disease severity is considered sufficient to cause substantial detriment to their immediate or future health or quality of life, according to at least one objective measure of disease severity appropriate for the patient's condition and age. The requested listing stated at least two measures of disease severity or quality of life impact must be used to assess impact on quality of life, of which at least one must be an objective measure.
- 4.4 The following IMiDs which may be treated with adalimumab were noted in the submission:
- inflammatory arthritides,
 - uveitis,
 - inflammatory bowel diseases,
 - psoriasis,

- rarer inflammatory diseases: sarcoidosis; chronic recurrent multifocal osteomyelitis; synovitis, acne, pustulosis, hyperostosis and osteitis syndrome; Behcet’s disease; juvenile dermatomyositis; chronic vasculitis; chronic erythema multiforme; pyoderma gangrenosum (PG); pyogenic arthritis, PG and acne (PAPA) and related neutrophilic dermatoses,
- acute, severe inflammatory conditions (short term use in the hospital setting): Stevens Johnson Syndrome, Toxic Epidermal Necrolysis, Toxic Shock Syndrome and Kawasaki disease.

4.5 The submission noted there are differences in treatment and outcomes in rural and regional Australia compared to metropolitan areas, and differences based on public versus private treatment and a patient’s socioeconomic status. There are also differences in medicines included in state and individual hospital formularies. The submission stated that including adalimumab on the PBS for paediatric indications could help to improve equitable access to effective treatment through removing geographic and facility-based barriers to treatment. It could also reduce pressure on hospitals and private clinics through reductions in in-patient care requirements, noting patients in remission will have reduced healthcare needs compared to those with active disease.

For more detail on PBAC’s view, see section 7 PBAC outcome.

5 Comparator

5.1 The submission did not nominate a comparator.

5.2 Any other medicine used for the management of IMIDs in paediatric patients could be considered comparators to adalimumab. These could include:

- For severe active juvenile idiopathic arthritis: etanercept, tocilizumab, tofacitinib, hydroxychloroquine, sulfasalazine.
- For moderate to severe ulcerative colitis and Crohn disease: infliximab, mesalazine, olsalazine, sulfasalazine.
- For complex refractory Fistulising Crohn disease: ustekinumab, infliximab.
- Psoriasis: acitretin, ustekinumab, etanercept.
- Azathioprine, mercaptopurine, methotrexate.

5.3 The PSCR disagreed that any other PBS-listed conventional or biological DMARDs could be considered comparators to adalimumab for the proposed population and place in therapy. It argued that as the proposed restriction is indication-agnostic and intended for children with the greatest risk of permanent disability and/or psychological distress, there were too many complex and multifarious factors to allow

for an appropriate comparator. The ESC considered that while this may be true for rare conditions, comparators are appropriate for the main indications of use.

For more detail on PBAC's view, see section 7 PBAC outcome.

6 Consideration of the evidence

Sponsor hearing

- 6.1 The sponsor requested a hearing for this item. Clinicians commented on the effectiveness of adalimumab for paediatric IMIDs, including rarer conditions, and presented clinical case studies of children presenting with IMIDs who would benefit from treatment with adalimumab but who would not be eligible to receive PBS subsidised therapy through the current PBS listings for adalimumab. Clinicians commented that earlier treatment with a biological medication was associated with better patient outcomes, disease remission, and prevention of long term complications. Challenges with daily activities (e.g. physical, social and education development) and quality of life for both the child and family were noted by the clinicians, and that earlier access to adalimumab would benefit these patients and their families. Clinicians stated that the requested listing would support patients to have more timely access to adalimumab, treatment would generally be used for 2 years before trialling a withdrawal, and that patients would only continue treatment with adalimumab if a benefit was seen.

Consumer comments

- 6.2 The PBAC noted and welcomed the input from individuals (6), health care professionals (3) and organisations (4) via the Consumer Comments facility on the PBS website. The comments noted the effectiveness of adalimumab for paediatric IMIDs in improving disease symptoms and quality of life, and that it could be easily administered. Comments also stated the current PBS restrictions for this medication did not reflect current practice, and did not allow use in all paediatric patients who would benefit from treatment. One comment stated that for rarer conditions there is a lack of robust research, and treatment approaches are based on consensus opinion. Comments were supportive of the requested listing, stating that it would allow access to adalimumab earlier in the treatment course and lead to better patient outcomes.
- 6.3 Comments stated the current PBS restrictions created delays in patients accessing adalimumab, which could worsen patient outcomes. This included the paperwork currently required to prescribe adalimumab through the PBS, which could delay treatment for patients.
- 6.4 Comments noted the financial strain to the family due to managing paediatric IMIDs, costs associated with accessing adalimumab when not living close to a hospital pharmacy supplying the medication (e.g. freight costs) and challenges with courier

services delivering the medication.

- 6.5 Some comments noted adverse effects experienced with adalimumab, however others stated it had a good safety profile and has been used for many years.

Clinical place for the proposed therapy

- 6.6 The submission outlined the following patient populations who may access adalimumab through the proposed indication-agnostic PBS-listing and provided the below justifications for the requested listing. This list was informed by expert opinion from clinician working groups comprising paediatric rheumatologists, gastroenterologists and dermatologists, and through a literature review.

- Inflammatory arthritides: the submission stated current PBS listings for paediatric juvenile idiopathic arthritis excludes patients with isolated sacroiliac and/or spinal disease (even though it is listed for ankylosing spondylitis in adults) and patients who have <4 active joints involved who have high risk of erosive disease (due to involvement of the hip, wrist, ankle, jaw/temporomandibular joint).
 - The Australian Paediatric Rheumatology Group and the Juvenile Arthritis Foundation stated in their submissions to the HoR Inquiry that specifying an arbitrary number of joints affected plus failure of methotrexate to access biologic treatment does not reflect the increased understanding of disease progression and potential benefits of early, aggressive treat-to-target approaches.
 - The American College of Rheumatology (ACR) Guidelines and NHS Policy Statement recommend anti-TNF agents as first line treatment for patients where sacroiliitis or axial arthritis is present.^{1,2}
 - The National Institute for Health and Care Excellence (NICE) recommendation for adalimumab (and etanercept) in juvenile idiopathic arthritis was inclusive of polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis and psoriatic juvenile idiopathic arthritis (with an acknowledgement that

¹ Ringold, S., S. T. Angeles-Han, et al, (2019), '2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis', *Arthritis Rheumatol* 71(6): pp. 846-863.

² Specialised Commissioning Team, NHS England, (2015), 'Clinical Commissioning Policy Statement: Biologic Therapies for the treatment of Juvenile Idiopathic Arthritis (JIA)', England E03X04. www.england.nhs.uk/wp-content/uploads/2018/08/Biologic-therapies-for-the-treatment-of-juvenile-idiopathic-arthritis.pdf and www.england.nhs.uk/wp-content/uploads/2018/07/Biologic-therapies-for-the-treatment-of-juvenile-idiopathic-arthritis-Appendix-A.pdf, accessed September 2023.

outcomes between populations was generalisable and based on clinical expert opinion).³

The submission claimed the requested PBS listing for adalimumab would be aligned with international best practice for these indications.⁴

- Uveitis: the submission stated that children with juvenile idiopathic arthritis-associated uveitis can currently only access adalimumab on the PBS if they meet the required number of swollen and tender joints. The submission claimed that uveitis is present in approximately 20% of patients with oligoarticular juvenile idiopathic arthritis and only 5% of patients with polyarticular juvenile idiopathic arthritis.⁵ The submission further claimed that in patients with oligoarticular juvenile idiopathic arthritis the uveitis can be more impactful in terms of disease severity compared to joint disease, and claimed that patients who would benefit the most from adalimumab cannot currently access it through the PBS.
 - Clinical practice guidelines produced by the ACR, the Single Hub and Access point for Paediatric Rheumatology in Europe (SHARE) and the Childhood Arthritis and Rheumatology Research Alliance (CARRA) recommend adalimumab as the first line biologic treatment for the treatment of juvenile idiopathic arthritis-associated uveitis in certain situations.^{6,7,8} The ACR guidelines conditionally recommend starting methotrexate and a monoclonal antibody TNF inhibitor immediately for children and adolescents with juvenile idiopathic arthritis with severe active chronic anterior uveitis and sight threatening complications over methotrexate monotherapy.⁶ The CARRA guidelines state that patients who fail methotrexate should be considered for the TNF inhibitor consensus treatment plan (3 months of treatment is

³ National Institute for Health and Care Excellence (NICE), (2015), 'Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis – Summary of Appraisal Committee's key conclusions', England TA373, www.nice.org.uk/guidance/ta373/chapter/4-Evidence-and-interpretation#summary-of-appraisal-committees-key-conclusions

⁴ Ravelli, A., A. Consolaro, et al, (2018), 'Treating juvenile idiopathic arthritis to target: recommendations of an international task force', *Annals of the Rheumatic Diseases* 77(6): pp. 819-828.

⁵ Heiligenhaus, A., K. Minden et al, (2015), 'Uveitis in juvenile idiopathic arthritis', *Dtsch Arztebl Int* 112(6): pp. 92-100.

⁶ Angeles-Han, S. T., S. Ringold, et al, (2019), '2019 American College of Rheumatology/Arthritis Foundation Guideline for the Screening, Monitoring, and Treatment of Juvenile Idiopathic Arthritis-Associated Uveitis', *Arthritis Care Res (Hoboken)* 71(6): pp. 703-16.

⁷ Angeles-Han, S. T., M. S. Lo, et al, (2019), 'Childhood Arthritis and Rheumatology Research Alliance Consensus Treatment Plans for Juvenile Idiopathic Arthritis-Associated and Idiopathic Chronic Anterior Uveitis', *Arthritis Care Res (Hoboken)* 71(4): pp. 482-91.

⁸ Constantin, T., I. Foeldvari, et al, (2018), 'Consensus-based recommendations for the management of uveitis associated with juvenile idiopathic arthritis: the SHARE initiative', *Ann Rheum Dis* 77(8): pp. 1107-17.

required before assessing methotrexate efficacy). If patients are not intolerant of methotrexate, a TNF inhibitor should be added to methotrexate (rather than replace). The TNF inhibitor consensus treatment plan can be considered for patients who are methotrexate-naïve with uncontrolled uveitis and severe disease, and methotrexate should be started simultaneously.⁷ Recommendations from the SHARE initiative state that TNF inhibitors (with adalimumab preferred) is recommended in patients with uveitis that is refractory or resistant to DMARD treatment (methotrexate).⁸ This is consistent with the recommendation from The Australian and New Zealand Juvenile Idiopathic Arthritis-Uveitis Working Group, which recommend methotrexate as the first choice of conventional systemic immunosuppressive drug, and adalimumab as the first choice of biologic systemic immunosuppressive drug.⁹

- The ACR guidelines recommend starting methotrexate and a monoclonal antibody TNFi immediately in children and adolescents with juvenile idiopathic arthritis with severe active chronic anterior uveitis and sight-threatening complications, over methotrexate monotherapy.
- The submission stated that patients with non-infectious uveitis of other aetiologies without joint involvement have limited options to access adalimumab, despite the potential risk of vision loss. The submission stated that the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) Paediatric, Glaucoma and Uveitis Special Interest Groups made a submission to the HoR Inquiry into Childhood Rheumatic Disease, with the suggestion that ‘adalimumab is PBS-listed for uveitis without joint involvement under the cotreatment of a paediatric rheumatologist.’
- Inflammatory bowel diseases: the submission claimed the inflammatory burden and disease severity in inflammatory bowel disease can be greater in paediatric patients compared to adults.
 - The submission stated for patients with high risk Crohn disease, in particular high-risk patients with perianal, stricturing or penetrating disease, or with severe growth retardation, international guidelines recommend the use of anti-TNF biologic therapies as first-line therapy, as well as proactive

⁹ Smith, J. R., J. M. Matthews, et al, (2021), ‘Recommendations for the management of childhood juvenile idiopathic arthritis-type chronic anterior uveitis’, *Clinical & Experimental Ophthalmology* 49(1): pp. 38-45.

therapeutic drug level monitoring and escalation of therapy where necessary to maintain trough levels within the therapeutic range.^{10,11}

- The submission stated that flexibility to optimise dosing in children with inflammatory bowel disease can have a steroid-sparing effect, potentially reducing steroid-related complications observed in children, and minimising side effects that can be of concern to patients (weight gain, insomnia, 'moon face').^{12,13} One of the references cited (Costello R et al) was a survey of adults, who rated weight gain as the most important adverse effect, followed by insomnia, 'moon face' and other adverse effects which were ranked at the same level of importance.
- Psoriasis: The submission stated that adalimumab is not currently PBS-listed for paediatric patients with chronic plaque psoriasis.
 - Patients can access etanercept and ustekinumab if they meet the disease severity and prior failed therapy criteria aligned to the existing adult restriction criteria (lesions present \geq 6 months; baseline psoriasis area and severity score (PASI) \geq 15; failure of 2 out of 3 conventional therapies). The submission stated these criteria are clinically inappropriate for paediatric patients, as children often present with significant involvement in isolated body areas (facial, scalp, nail) which is visually confronting and functionally debilitating (hands and feet)¹⁴, but with insufficient body surface area involved to meet the PASI threshold. There can be practical challenges to using phototherapy in children, such as school absenteeism and fear of isolation in the phototherapy cabinet.
 - The submission stated that delays in initiating an effective biologic treatment for chronic plaque psoriasis can lead to significant comorbidities and psychological impact, including a higher prevalence of obesity, diabetes

¹⁰ van Rheenen, P. F., M. Aloï, et al, (2020), 'The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update', J Crohns Colitis: jjaa161.

¹¹ Assa, A., M. Matar, et al, (2019), 'Proactive Monitoring of Adalimumab Trough Concentration Associated With Increased Clinical Remission in Children With Crohn's Disease Compared With Reactive Monitoring', Gastroenterology 157(4): pp. 985-996.e982.

¹² Uchida, K., T. Araki, et al, (2006), 'Preoperative steroid-related complications in Japanese pediatric patients with ulcerative colitis', Dis Colon Rectum 49(1): pp. 74-9.

¹³ Costello, R., R. Patel, et al, (2017), 'Patient perceptions of glucocorticoid side effects: a cross-sectional survey of users in an online health community', BMJ Open 7(4): e014603.

¹⁴ Bronckers, I. M., A. S. Paller, et al, (2015), 'Psoriasis in Children and Adolescents: Diagnosis, Management and Comorbidities', Paediatr Drugs 17(5): pp. 373-84.

mellitus, hypertension, juvenile arthritis, Crohn disease and psychiatric disorders.^{14,15}

- The submission stated that adalimumab could also be used for guttate psoriasis flares and acute pustular psoriasis flares that require hospitalisation and treatment with methotrexate (with adalimumab supporting earlier discharge and return to normal family function, and ongoing outpatient treatment and management).
- Rarer autoinflammatory diseases: The submission stated there are a number of less common IMIDs where adalimumab may be used in clinical practice in Australia (summarised in paragraph 4.4). The submission claimed making adalimumab accessible for these patients through the proposed indication-agnostic listing would help address inequities in access to effective treatments for these children.
- Acute, severe inflammatory conditions: The submission stated clinician working groups identified a number of conditions where adalimumab may be used in hospitalised patients, based either on evidence available in the literature or personal clinical experience (outlined in paragraph 4.4). It is anticipated by the experts that these conditions would require short-term use of adalimumab.

Clinical evidence

- 6.7 The submission presented a literature search which it stated focused on the evidence for adalimumab for the treatment of paediatric indications. The literature search found 17 randomised controlled trials (including phase 3 registrational studies) and 6 non-randomised interventional trials in open-label extension studies (Table 1).

¹⁵ Pinson, R., B. Sotoodian et al, (2016), 'Psoriasis in children', *Psoriasis (Auckl)* 6: pp. 121-9.

*Public Summary Document – March 2024 PBAC Meeting with Corrigendum and December 2024 addendum
Committee In Confidence*

Table 1: Trials presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
Randomised controlled trials		
EudraCT 2007-003358-27	Horneff G, Fitter S, et al. Double-blind, placebo-controlled randomized trial with adalimumab for treatment of juvenile onset ankylosing spondylitis (JoAS): significant short term improvement	Arthritis Res Ther. 2012; 14(5): R230
NCT00409682 IMAgINE-1	Efficacy and Safety of Adalimumab in Pediatric Subjects With Moderate to Severe Crohn's Disease	2011
NCT00048542	Study of Human Anti-TNF Monoclonal Antibody Adalimumab in Children With Polyarticular Juvenile Idiopathic Arthritis (JIA)	2020
NCT01166282	A Study of the Efficacy and Safety of Adalimumab in Pediatric Subjects With Entesitis Related Arthritis	2016
NCT01251614	A Double Blind Study in Pediatric Subjects With Chronic Plaque Psoriasis, Studying Adalimumab vs. Methotrexate	2013
NCT01385826	Effect of Adalimumab for the Treatment of Uveitis in Juvenile Idiopathic Arthritis (ADJUVITE)	2015
NCT02065557 ENVISION-1	Croft NM, Faubion Jr WA, et al. Efficacy and safety of adalimumab in paediatric patients with moderate-to-severe ulcerative colitis (ENVISION I): a randomised, controlled, phase 3 study	Lancet Gastroenterol Hepatol. 2021; 6(8):616-27.
NCT02256462	Pediatric Crohn's Disease Adalimumab Level-based Optimization Treatment (PAILOT) Trial	2018
NCT02772965 COMBINE	Low Dose Oral Methotrexate in Pediatric Crohn's Disease Patients Initiating Anti-Tumor Necrosis Factor (Anti-TNF) Therapy (COMBINE)	2023
NCT02840175	Treatment Tapering in JIA With Inactive Disease (AJIBIOREM)	2020
NCT02852694	Reduce Risk for Crohn's Disease Patients	2022
NCT03816397 ADJUST	Acharya NR, Ebert CD, et al. Discontinuing adalimumab in patients with controlled juvenile idiopathic arthritis-associated uveitis (ADJUST-Adalimumab in Juvenile Idiopathic Arthritis-associated Uveitis Stopping Trial): study protocol for a randomised controlled trial	Trials. 2020; 21(1):887.
NCT03828019 ADVISE	Adalimumab vs. Conventional Immunosuppression for Uveitis Trial (ADVISE)	In progress
NCT04646187	De-escalation of Anti-TNF Therapy in Inflammatory Bowel Disease (FREE)	In progress
NCT05015335	The Efficacy and Safety of Adalimumab in Non-infectious Anterior Pediatric Uveitis With Peripheral Vascular Leakage	2021
	Polgreen LE, Kunin-Batson A, et al. Pilot study of the safety and effect of adalimumab on pain, physical function, and musculoskeletal disease in mucopolysaccharidosis types I and II	Mol Genet Metab Rep. 2017; 75-80.
SYCAMORE ISRCTN10065623 EudraCT 2010-021141-41	A randomised controlled trial of the clinical effectiveness, safety and cost-effectiveness of adalimumab in combination with methotrexate for the treatment of juvenile idiopathic arthritis associated uveitis (SYCAMORE Trial)	Trials. 2014; 15:14.
Non-randomised interventional trials		
NCT00775437	Active Juvenile Idiopathic Arthritis (JIA) Compassionate Use	2013
NCT00686374	Efficacy and Long Term Safety of Adalimumab in Pediatric Subjects Who Have Demonstrated Clinical Response in M06-806	2017
NCT02632175	Long-term Safety and Efficacy Study of Adalimumab in Pediatric Subjects With Ulcerative Colitis	In progress
NCT04588818	Adalimumab Plus Methotrexate for the Treatment of Pediatric Uveitis	2023
NCT05540743	Biologic Therapy in Pediatric JIA Uveitis	In progress
NCT00690573	Safety, Efficacy, and Pharmacokinetics of Adalimumab in Japanese Children With Juvenile Rheumatoid Arthritis	2011

Source: Submission: A_Summary Systematic Literature Review

- 6.8 The literature search found adalimumab had been studied for the treatment of:
- inflammatory arthritides in 173 paediatric patients
 - inflammatory bowel disease in 457 patients
 - non-infectious uveitis in 76 patients
 - plaque psoriasis in 77 patients
 - mucopolysaccharidosis types I and II in 1 patient.
- 6.9 In addition, the literature search found 253 observational studies and 76 case series and reports reviewing efficacy outcomes, 105 observational studies looking at safety outcomes, and 72 reviews on both safety and efficacy. The submission stated the published observational evidence for the use of adalimumab included:
- 3,382 children with inflammatory arthritides (including polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, juvenile psoriatic arthritis, sacroiliitis, and axial spondyloarthritis)
 - 5,438 children with inflammatory bowel disease (including very early onset inflammatory bowel disease, ulcerative colitis, Crohn disease and associated phenotypes)
 - 1,311 children with uveitis of all aetiological origins
 - 392 children with either plaque, pustular or rupioid psoriasis
 - 93 patients with other rare auto-inflammatory diseases or acute inflammatory conditions.
- 6.10 The submission further stated that the literature search also identified 92 observational studies with safety-related endpoints, encompassing 4,914 patients globally.
- 6.11 The ESC noted the literature provided primarily focused on the safety of adalimumab rather than efficacy in particular conditions, and also included real world data. The pre-PBAC response disagreed with this, and claimed evidence provided investigated both efficacy and safety outcomes.
- 6.12 The ESC noted the Juvenile Arthritis Foundation Australia’s IMPACT (Investigating the Mental, Physical, Social and Financials CosTs) study¹⁶ and its main findings, and the impacts of childhood rheumatic diseases on patients including therapy, costs and

¹⁶ Bond DM, Von Huben A, Lain S, et al (2023), *The IMPACT Study: Investigating the Mental, Physical, Social And Financial CosTs (IMPACT) of Juvenile Idiopathic Arthritis and Related Childhood Rheumatic Diseases*, Juvenile Arthritis Foundation Australia, Sydney.

quality of life. The ESC noted that juvenile idiopathic arthritis led to a significant reduction in quality of life.

Comparative effectiveness

6.13 The submission did not provide any study results comparing the safety and efficacy of adalimumab to other treatments for the treatment of paediatric IMIDs. However, the submission did provide the following information regarding the use of adalimumab compared to other therapies for certain conditions:

- Inflammatory bowel diseases:
 - azathioprine is generally an effective first-line immunosuppressive treatment for ulcerative colitis. However, this is not the same for conventional immunosuppressive treatments mandated in Crohn disease (especially in high-risk patients with perianal, stricturing or penetrating disease, or with severe growth retardation). International guidelines recommend the use of anti-TNF biologic therapies first-line in these high-risk patients.
 - Flexibility to optimise dosing in children with inflammatory bowel disease can have a steroid-sparing effect, reducing the risk of adverse effects from corticosteroids such as weight gain, insomnia and ‘moon face’.
- Uveitis:
 - The ACR guidelines recommend starting combination therapy with a monoclonal antibody TNFi in conjunction with methotrexate in children and adolescents with juvenile idiopathic arthritis with severe active chronic anterior uveitis and sight-threatening complications, compared to methotrexate monotherapy.

Safety considerations

6.14 The Humira Product Information states: ‘The safety and efficacy of Humira has not been established in other forms of juvenile idiopathic arthritis (JIA) such as systemic JIA or oligoarticular JIA. The long term effects of Humira on the growth and development of children have not been studied. Treatment with Humira should only be initiated in patients with paediatric Crohn’s disease following diagnosis by a specialist gastroenterologist, where other diseases with potentially similar presentations (e.g., Inflammatory Bowel Disease (IBD) associated with chronic granulomatous disease) have been ruled out. Humira has not been studied in children with Crohn’s disease aged less than 6 years.’

6.15 The submission cited a publication by Horneff et al, which was an analysis of safety events across 7 randomised and open-label trials of adalimumab and their open-label

extensions (Horneff et al, 2018)¹⁷. There were 577 paediatric patients included in the analysis, representing 1,440.7 patient-years of adalimumab exposure across polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, chronic plaque psoriasis and Crohn disease:

- The most commonly reported adverse events (events/100 patient-years (PY)) were upper respiratory tract infections (24.3/100 PY), nasopharyngitis (17.3/100 PY), and headache (19.9/100 PY).
- Serious infections (4.0/100 PY) were the most frequent serious adverse events across indications; the most commonly reported was pneumonia (0.6/100 PY). Serious infection rates were 2.7, 0.8, and 6.6/100 PY in patients with juvenile idiopathic arthritis, psoriasis and Crohn disease, respectively.
- No events of malignancies were reported.
- One death (accidental fall) occurred in a patient with psoriasis.

6.16 The submission provided the Update to the Periodic Safety Update Report for: Adalimumab (reporting interval of 1 January 2023 to 30 June 2023), which stated that there was no new efficacy or safety information received that had a significant impact on the benefit/risk evaluation of adalimumab.

6.17 The report stated that there was one new safety signal identified during the interval, outlined in Table 2.

¹⁷ Horneff G., M.M.B. Seyger, et al (2018), 'Safety of Adalimumab in Pediatric Patients with Polyarticular Juvenile Idiopathic Arthritis, Enthesitis-Related Arthritis, Psoriasis, and Crohn's Disease', J Pediatr 201:pp. 166-75.e3

Table 2: Safety signals (closed or ongoing) during the PSUR Update Reporting Interval 1 January 2023 through 30 June 2023

Signal Term	Neuropsychiatric disorders
Date Detected	21 February 2023
Status (New, Ongoing or Closed)	Closed
Date Closed (for Closed Signals)	12 May 2023
Source of Signal	FDA
Reason for Evaluation and Summary of Key Data	On 21 February 2023, AbbVie received a Request for Information from the FDA for a comprehensive analysis of specific neuropsychiatric adverse events coincident with adalimumab and a cumulative summary of drug utilization rates for adalimumab in the United States and worldwide
Method of Signal Evaluation	Case Series Analysis ^a
Action(s) Taken or Planned	Signal not confirmed. There is no evidence of a causal relationship between the neuropsychiatric medical concepts of suicide, depression, anxiety, delirium/disorientation or hallucinations/paranoia/acute psychosis/psychotic disorder/mania and adalimumab based on clinical trial data and postmarketing reports. No changes to the CCDS or Risk Management Plan are recommended at this time. The data reviewed in this report do not change the established benefit risk profile of adalimumab, which remains favorable

Source: Attachment 4 ADA 30 June 2023 PSUR Update

AbbVie: AbbVie Inc.; CCDS: Company Core Data Sheet; FDA: Food and Drug Administration; PSUR: Periodic Safety Update Report

^aCase Series Analysis: MAH standardized analysis includes review of cases from MAH postmarketing and clinical trial databases and literature

- 6.18 The report stated that there had been no actions taken for safety reasons during the interval covered by this update.
- 6.19 A benefits and harms table is not presented as the submission did not make a clinical claim.
- 6.20 The ESC noted that a broad listing for adalimumab with no restrictions on indications differs from the listings for similar medicines. It expressed concern about broadening the listing to include conditions in which efficacy has not been established, given the drug is not without risks (known adverse events and immunosuppressive effects), the extent of which are unclear in the paediatric setting. The ESC also noted that there were different levels of evidence for the use of adalimumab in children for different indications.

Clinical claim

- 6.21 The submission did not include a clinical claim.

Economic analysis

- 6.22 The submission did not provide an economic analysis.
- 6.23 The PSCR stated ‘While the cost-effective price of adalimumab (Humira) has not been formally established in these patient groups, AbbVie refers to the NICE

recommendation for adalimumab and etanercept in JIA,¹⁸ which was inclusive of polyarticular juvenile idiopathic arthritis (pJIA), enthesitis-related arthritis (ERA) and psoriatic JIA, where it was acknowledged that the outcomes between populations were overall generalisable and therefore likely to be equally cost-effective at a given price.’

- 6.24 The ESC noted that as there was no economic analysis presented for any of the proposed indications there was no basis for assessing cost-effectiveness. No reference points of previous decisions were nominated. A parallel application for adalimumab for uveitis, which is a relative common feature of some of the indications in this submission, presented a cost-effectiveness analysis with a base incremental cost-effectiveness ratio (ICER) of \$25,000 to < \$35,000. That ICER was very sensitive to time horizon and assumed ocular benefits and a specific disease duration. When used in younger patients, adalimumab is likely to be used for a longer period compared to older patients, considering that treatment will be started earlier and in most situations, adalimumab will be used to control (rather than cure) the condition.
- 6.25 The submission requested the following dispensed price for maximum quantity (DPMQ) for the different strengths of Humira:

Table 3: Requested DPMQ for Humira

Listing	Maximum quantity (packs)	Maximum quantity (units)	Requested DPMQ
Initial treatment			
80 mg in 0.8 mL pre-filled syringe 80 mg in 0.8 mL pre-filled pen	3	3	\$2,014.38
40 mg in 0.4 mL pre-filled syringe 40 mg in 0.4 mL pre-filled pen	2	4	\$1,345.59
20 mg in 0.2 mL pre-filled syringe	1	2	\$706.70
Continuing treatment			
80 mg in 0.8 mL pre-filled syringe 80 mg in 0.8 mL pre-filled pen	2	2	\$1,345.59
40 mg in 0.4 mL pre-filled syringe 40 mg in 0.4 mL pre-filled pen	2	4	\$1,345.59
20 mg in 0.2 mL pre-filled syringe	2	4	\$1,345.59

Source: Attachment 2: ADA Paed IMIDs Proposed Restrictions

DPMQ: dispensed price for maximum quantity

- 6.26 All requested DPMQs are consistent with the current DPMQ for the General Schedule listings of Humira as of January 2024 for the respective strengths and quantities, with the exception of the requested DPMQ for the 20 mg in 0.2 mL pre-filled syringe. There is currently no PBS-listing for this strength with a maximum quantity of 4 units. The

¹⁸ National Institute for Health and Care Excellence (NICE), (2015), ‘Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis – Summary of Appraisal Committee’s key conclusions’, England TA373, www.nice.org.uk/guidance/ta373/chapter/4-Evidence-and-interpretation#summary-of-appraisal-committees-key-conclusions

current DPMQ for Humira 20 mg in 0.2 mL pre-filled syringe for a maximum quantity of 2 units is \$706.70.

Drug cost/patient/year

6.27 Table 4 outlines the maximum drug cost per patient per year based on the indication, assuming the highest recommended dose and induction treatment.

Table 4: Maximum drug cost per patient per year based on indication

Indication	Maximum dose	Cost/patient/month	Cost/patient/year
Juvenile idiopathic arthritis	40 mg every 2 weeks	\$672.80	\$8,746.40
Enthesitis-related arthritis	40 mg every 2 weeks	\$672.80	\$8,746.40
Crohn disease	Induction: 160 mg (Day 0), 80 mg (Day 14) Maintenance: 80 mg every 2 weeks	Month 1: \$2,014.38 Month 2 onwards: \$1,345.59	\$18,161.46
Ulcerative colitis	Induction: 160 mg (Day 0), 80 mg (Day 14) Maintenance: 40 mg every 2 weeks	Month 1: \$2,014.38 Month 2 onwards: \$672.80	\$10,087.98
Psoriasis	Induction: 40 mg (Week 0), 40 mg (Week 1) Maintenance: 40 mg every 2 weeks (from week 3)	Month 1: \$1,345.59 Month 2 onwards: \$672.80	\$9,419.19
Hidradenitis suppurativa	Induction: 80 mg Maintenance: 80 mg every 2 weeks (from Week 1)	Month 1: \$2,014.38 Month 2 onwards: \$1,345.59	\$18,161.46
Uveitis	Induction: 80 mg Maintenance: 40 mg every 2 weeks (from Week 1)	Month 1: \$1,345.59 Month 2: \$672.80	\$9,419.19

Source: Based on requested DPMQ in Attachment 2 of the submission

Estimated PBS usage & financial implications

6.28 This submission was not considered by DUSC.

6.29 The PSCR provided estimates of expected use and financial implications for the first 6 years of listing (see Table 5). The PSCR stated that estimates are based on expert opinion and available evidence, and considered that estimates are likely to be over-estimated as they do not account for future price reductions.

Table 5: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use (all strengths)						
Number of patients treated	1 ¹	1	2	2	2	2
Number of scripts dispensed ^a	2	3	3	3	3	3
Estimated financial implications of adalimumab (all strengths)						
Cost to PBS/RPBS less copayments	4	4	4	4	4	5

Source: Utilisation and cost workbook

^a Assuming 12 scripts per year as estimated by the submission.

The redacted values correspond to the following ranges:

¹ < 500

² 500 to < 5,000

³ 5,000 to < 10,000

⁴ \$0 to < \$10 million

⁵ \$10 million to < \$20 million

- 6.30 The total cost to the PBS/RPBS of listing adalimumab for the requested restriction was estimated to be \$10 million to < \$20 million in Year 6, and a total of \$50 million to < \$60 million in the first 6 years of listing. The ESC considered this to be uncertain but plausible.
- 6.31 The estimated financial implications do not account for any potential financial implications of other PBS-listed medicines if adalimumab replaces the use of other therapies.
- 6.32 The PSCR stated the proposed population estimates include, but are not limited to, patients who have been diagnosed with an IMID for which adalimumab is currently PBS-listed but who do not meet the eligibility requirements of the existing restrictions. The estimates do not include patients with uveitis. The ESC considered this is likely to cover the majority of potentially eligible patients.
- 6.33 The submission estimated a minor increase in uptake of adalimumab by the paediatric population relative to the whole population currently accessing treatment with adalimumab through the PBS. It estimated 500 to < 5,000 additional paediatric patients would access adalimumab through the requested listing (< 500 patients through the grandfather listing and < 500 new patients) (Table 6).

Table 6: Estimated patient numbers based on state/territory and condition

Tertiary Institution	State	Relative proportion	Dermatology		Gastro IBD (CD & UC)	Rheumatology		Grandfather
			PsO	Other		Inflammatory arthritides & uveitis	Other	
TCH Westmead	NSW	1	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
SCH Randwick	NSW		█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
Monash Children's Hospital	VIC	0.8	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
RCH Melbourne	VIC		█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
Queensland Children's Hospital	QLD	0.7	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
Women's and Children's Hospital Adelaide	SA	0.2	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
Perth Children's Hospital	WA	0.4	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
n/a	TAS	0.1	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
n/a	NT	0.03	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
n/a	ACT	0.1	█████ ¹	█████ ¹	-	█████ ¹	█████ ¹	
Sum total			█████ ¹	█████ ¹	█████ ^{1a}	█████ ¹	█████ ¹	█████ ^{1b}
Total								█████ ^{1c}

Source: Attachment 5 ADA Paed IMID patient estimates

ACT: Australian Capital Territory; CD: Crohn disease; Gastro: gastroenterology; IBD: inflammatory bowel disease; n/a: not applicable; NSW: New South Wales; NT: Northern Territory; PsO: psoriasis; QLD: Queensland; RCH: The Royal Children's Hospital; SA: South Australia; SCH: Sydney Children's Hospital; TAS: Tasmania; TCH: The Children's Hospital; UC: ulcerative colitis; VIC: Victoria; WA: Western Australia

^a For IBD patients, it is anticipated that the proposed restriction criteria will not expand the eligible population (aside from a small number of patients < 6 years old), rather will be used to treat high-risk patients earlier in their disease course, without the need to fail systemic immunosuppressants first. Therefore, this estimate is based on approximately 10% of the existing utilisation in across both CD and UC, and will be essentially cost neutral as these patients will access treatment via the IMID restriction, rather than via the existing CD or UC restrictions.

^b Expert opinion has indicated that their estimates are inclusive of existing compassionate supply patients therefore this has been factored into overall estimates.

^c The submission provided a total of <500 patients. This has been updated to <500 to reflect the patient numbers provided for the different conditions. Excludes estimated number of patients in the grandfather category

The redacted values correspond to the following ranges:

¹ <500

6.34 The submission stated that as the assessment of treatment eligibility is individualised and based on clinician judgement, the estimated number of patients who would be treated under the proposed restrictions was informed by expert opinion based on their current patient population. The estimates are informed by expert clinical opinion and may not account for differences in individual prescribing practices. Furthermore, as the requested listing involves subjective assessment from individual prescribers. The number of patients accessing adalimumab through the requested listing could be higher than estimated.

6.35 The PSCR argued that the estimated patient numbers provided the best approximation given the lack of Australian epidemiological and registry data for

paediatric patients. It stated that clinicians working in both public and private practice, and in metropolitan and regional services, were asked to provide estimates of patient numbers. It stated that the number of paediatric specialists and paediatric hospitals in Australia is small and variability in evidence-based prescribing was minimal.

- 6.36 It was considered that for the rarer auto-inflammatory diseases the number of patients is low and as such the potential utilisation may be slightly overestimated due to the numerical rounding of estimates for less-populated states and territories.
- 6.37 The submission stated that following the initial period of higher uptake driven by the prevalent patient population, the number of incident patients could be reasonably expected to decrease over subsequent years before stabilising.
- 6.38 The estimated number of patients accessing Humira through the grandfather listing was based on the number of patients currently receiving compassionate access to Humira on a continuing basis across all indications. The submission stated they were not aware of any other programs supplying adalimumab to paediatric patients on compassionate access programs.
- 6.39 The submission estimated the number of patients treated for rarer inflammatory diseases (outlined in paragraph 4.4) is low, with fewer than 5 patients across all conditions reviewed each year at the major children's hospitals.
- 6.40 The ESC noted there was a lack of information on potential impact on use of adalimumab if paediatric patients currently accessing other PBS-listed bDMARDs do not meet the response or other criteria for these listings, and subsequently access adalimumab through the requested listing. The PSCR stated it was not the intent of the requested listing to allow patients who access and subsequently fail to respond to another PBS-subsidised biological treatment for an IMiD to then access adalimumab through the requested listing (see paragraph 3.5).
- 6.41 The submission claimed that any budget impact would be minimal due to the small number of patients relative to the current reimbursed populations in both paediatric and adult patients. However, regardless of the relative cost, the financial impact of the proposed change needs to be considered. The submission further claimed any costs would be outweighed by the potential benefits of treating these patients and alleviating the burden of disease for these patients and their families. This has not been modelled through an economic evaluation.
- 6.42 The ESC considered the utilisation and financial estimates presented in this submission were complex and uncertain. For conditions where there is already a listed indication, the numbers are likely to be reasonable estimates. However, the proposed listing allows substantial clinician discretion which makes estimates of uptake difficult to predict. For conditions outside of these listed indications, there is a high level of uncertainty due to a limited and uncertain evidence base. However, in a paediatric

population, deviation from the financial and utilisation estimates is likely to be relatively small.

- 6.43 The submission claimed that the Humira brand of adalimumab, at its current price, is more cost-effective than when it was first PBS-listed for patients with juvenile idiopathic arthritis, with a 48% reduction in the effective approved ex-manufacturer price (AEMP) due to statutory price reductions. The submission stated that the reduction in price is expected to continue due to price disclosure, thereby increasing the cost-effectiveness of increased access, and that with the lower price adalimumab is likely to be cost-effective in the requested expanded populations.
- 6.44 The proposed listing may include a patient population with less severe disease, or who have received fewer prior treatments for their condition, compared to the current PBS-listed indications for adalimumab. While the likelihood of cost-effectiveness increases with decreasing prices, the cost-effective price of adalimumab has not been established in these patient groups.
- 6.45 The PSCR argued that the requested listing would not include patients with less severe diseases, but would allow children with aggressive, severe disease to receive treatment with adalimumab earlier in their disease course to prevent disease progression and limit long term disability and psychological impact. It argued that this is a small, but critical, group of patients that paediatric specialists can identify through an overall assessment of their current disease course, biomarkers, pathophysiological features and through the individual prescriber's experience and judgement. The PSCR stated that the majority of clinicians who would prescribe adalimumab under the requested restriction would be experienced in the management of paediatric IMIDs. It argued that it would be unlikely that prescribers would choose to use adalimumab in patients whose disease severity and/or impact on quality of life was not severe enough to warrant the benefit-risk profile of adalimumab, nor would they be likely to continue treatment if the patient was not receiving benefit.
- 6.46 The PSCR stated that while the cost-effective price of adalimumab had not been formally established in these patient groups, it requested the PBAC consider the 48% reduction in AEMP for Humira and the further 18.25% price reduction occurring in April 2024. It reiterated its claim that at the reduced price Humira is a cost-effective treatment.

For more detail on PBAC's view, see section 7 PBAC outcome.

7 PBAC Outcome

- 7.1 The PBAC deferred making a recommendation to list adalimumab (Humira) on the PBS as a General Schedule Authority Required (STREAMLINED) listing for the treatment of IMIDs in paediatric patients to allow further consultation with relevant clinical groups.

- 7.2 The PBAC noted the recommendations from the Inquiry into childhood rheumatic diseases: Interim report and consumer comments supporting increased access to adalimumab through the PBS for paediatric conditions. The PBAC acknowledged the importance of access to adalimumab through the PBS for conditions in which there is evidence for its use.
- 7.3 The PBAC noted that the submission covered situations where there was no PBS listing for a particular IMID, and situations where adalimumab was listed on the PBS for a condition, but the clinical criteria may not be suitable for paediatric presentations of the disease.
- 7.4 The PBAC noted that IMID was not a condition on its own, and the requested listing encompassed some conditions where adalimumab was TGA registered and there was evidence available for the efficacy of adalimumab, and some rarer conditions for which adalimumab was not TGA-registered. The PBAC noted the submission did not provide any evidence for the use of adalimumab in these rarer non-registered conditions. The PBAC considered that for these rarer conditions use would most commonly occur in hospitals as inpatient use. The PBAC therefore advised that it would not be appropriate to list adalimumab for the proposed broad IMID indication. However, the PBAC advised that for those indications where there was evidence for the use of adalimumab in children, unnecessary barriers to accessing adalimumab on the PBS should be removed.
- 7.5 The PBAC noted the following conditions were TGA-registered indications for adalimumab, and adalimumab was currently PBS-listed for these indications to allow use in children: hidradenitis suppurativa, juvenile idiopathic arthritis, ulcerative colitis and Crohn disease. For some conditions there were also multiple alternatives available on the PBS. The PBAC recalled that at its March 2016 meeting it had recommended an age-agnostic listing for adalimumab for moderate to severe ulcerative colitis, where the sponsor had previously requested restricting the listing to adults only.
- 7.6 The PBAC noted that a separate request to list adalimumab for the treatment of patients with vision-threatening non-infectious uveitis was being considered at the same PBAC meeting.
- 7.7 The PBAC therefore considered ankylosing spondylitis should be its focus as the only condition for which there was sufficient evidence for using adalimumab where the PBAC had not made a recommendation to allow use in children.
- 7.8 The PBAC acknowledged potential barriers with the current PBS listings of adalimumab for paediatric patients. For example, the clinical criteria specified in the current adult listing for ankylosing spondylitis were not appropriate requirements for children with this condition, and the maximum doses allowed in the listings for Crohn disease and ulcerative colitis may not reflect current clinical practice. As such, age-agnostic listings that do not consider the restriction criteria from a paediatric

perspective are not sufficient.

- 7.9 The PBAC was therefore of a mind to recommend changes to the current listings of adalimumab for ankylosing spondylitis, ulcerative colitis and Crohn disease to reflect available evidence and current clinical practice in paediatric patients. However, the PBAC required further clinical input before making such recommendations. The PBAC requested the Department engage with relevant clinical groups to review the current eligibility criteria for the PBS listings of adalimumab for ankylosing spondylitis, ulcerative colitis and Crohn disease, and revise these where necessary so that they reflect current evidence and clinical practice. The revised listings would be brought to the PBAC for further consideration.

Outcome:

Deferred

8 Corrigendum

The following changes were made:

Change made	Date of revision
Paragraph 7.5: conditions for which adalimumab is PBS-listed to allow use in children updated to remove the conditions 'psoriatic arthritis' and 'plaque psoriasis' (these conditions are not PBS-listed for paediatric patients)	11 December 2024

9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

10 Sponsor's Comment

Existing PBS listings for certain immune-mediated inflammatory diseases do not reflect paediatric disease presentations or current clinical practice. AbbVie is disappointed that the PBAC did not accept the request for a broad indication for IMIDs, however remains committed to continuing to work with all stakeholders to expedite removal of existing barriers to earlier, expanded access so that Australian children with certain IMIDs can realise better disease, quality of life, and life-course outcomes as soon as possible.

*Public Summary Document – March 2024 PBAC Meeting with Corrigendum and December
2024 addendum
Committee In Confidence*

Addendum to the March 2024 PBAC PSD:

4.02 ADALIMUMAB,

**Injection 20 mg in 0.2 mL pre-filled syringe,
Injection 40 mg in 0.4 mL pre-filled syringe,
Injection 40 mg in 0.4 mL pre-filled pen,
Injection 80 mg in 0.8 mL pre-filled syringe,
Injection 80 mg in 0.8 mL pre-filled pen,
Humira[®],
AbbVie Pty Ltd.**

11 Purpose of Submission

- 11.1 For the Pharmaceutical Benefits Advisory Committee (PBAC) to consider advice provided by clinical groups on the current PBS listings and eligibility criteria for adalimumab (Humira[®]) and whether they reflect current evidence and practice in the management of paediatric immune-mediated inflammatory disease (IMID).
- 11.2 For the PBAC to consider proposed revised and new PBS listings for Humira for paediatric IMID conditions for which there is evidence for the use of adalimumab. This includes:
- Proposed revised listings for adalimumab for the treatment of moderate to severe ulcerative colitis and severe Crohn disease.
 - Whether adalimumab should be listed on the PBS for the treatment of patients with enthesitis related juvenile idiopathic arthritis.
 - Whether adalimumab should be listed on the PBS for the treatment of paediatric patients with severe chronic plaque psoriasis, and its place in therapy for this indication if recommended.
- 11.3 For the PBAC to consider if adalimumab is cost-effective at the proposed revised and new listings.

12 Background

- 12.1 At its March 2024 meeting, the PBAC considered a request from the sponsor of Humira, AbbVie Pty Ltd, to list Humira as a General Schedule Authority Required (STREAMLINED) listing for the treatment of IMID in paediatric patients. The submission requested that adalimumab be PBS-listed as an indication-agnostic listing

to allow patients with the greatest risk of permanent disability and/or psychological distress to receive treatment with adalimumab.

- 12.2 The PBAC deferred making a recommendation to allow further consultation with relevant clinical groups. It noted that IMID is not a condition in itself and that it covers a broad range of conditions, including rarer conditions. The PBAC further noted that adalimumab is not TGA-registered for all these indications and that there is varying levels of evidence for the use of adalimumab in different IMIDs.
- 12.3 The PBAC advised that for those indications where there is evidence for the use of adalimumab in children, unnecessary barriers to accessing adalimumab on the PBS should be removed. The PBAC considered that ankylosing spondylitis was the main condition where there was evidence for the use of adalimumab in children, however it is not currently PBS-listed for this indication for use in children. The PBAC also noted that current PBS-listed maximum doses for adalimumab for Crohn disease and ulcerative colitis in children may not reflect current practice.
- 12.4 The PBAC requested the Department engage with relevant clinical groups to review the current eligibility criteria for the PBS listings for adalimumab for paediatric IMID indications and revise these listings where required to reflect current evidence and practice. The PBAC requested that these revised listings be brought to the PBAC for further consideration.
- 12.5 The Department requested advice from the following clinical groups: Australian Rheumatology Association (ARA), Australian Paediatric Rheumatology Group (APRG), Crohn's and Colitis Australia (CCA), Gastroenterological Society of Australia (GESA), Royal Australasian College of Physicians, and The Australasian College of Dermatologists (ACD).
- 12.6 Advice was also sought from clinicians (5 gastroenterologists) who gave input for the sponsor's submission and provided contact details.

For more detail on PBAC's view, see section 16 PBAC outcome.

13 Clinical advice

- 13.1 The Department received responses from four organisations (the ARA (in conjunction with the APRG), CCA, GESA and ACD) and two individuals (gastroenterologists).
- 13.2 Advice was also received from a rheumatologist, who noted that for some IMIDs, the disease may subside for some paediatric patients.

Ankylosing spondylitis

- 13.3 The ARA provided the following advice regarding the use of adalimumab for ankylosing spondylitis in paediatric patients:

- There is a strong need to improve access to treatment for children with enthesitis/spondylitis related juvenile idiopathic arthritis (ERA). It is associated with a worse quality of life compared to other types of juvenile idiopathic arthritis, has lower response rates to conventional treatments, and a higher rate of permanent joint damage.
- Evidence demonstrates that adalimumab is a safe and effective treatment for ERA and is considered a standard treatment internationally.
- Non-steroidal anti-inflammatory drugs (NSAIDs) are recommended for initial treatment for ERA. Conventional DMARDs (csDMARDs) (e.g. methotrexate) do not have a role in the management of axial disease but can be helpful for peripheral arthritis and enthesitis. Tumour necrosis factor inhibitors (e.g. adalimumab) are recommended for children and young people with active sacroiliitis disease despite NSAIDs.
- csDMARDs (e.g. methotrexate, sulfasalazine) are not effective for treating axial disease and corticosteroid injections generally only provide short term improvement for sacroiliitis. It is therefore proposed that active inflammatory axial disease (sacroiliitis and/or spondylitis) that is not responding to NSAIDs and physiotherapy is an indication for the use of adalimumab.
- While classification criteria and disease activity scores have been developed for ERA, there are no validated cut-off values to define active or inactive disease. The ARA proposed that a juvenile spondyloarthritis disease activity index score of >2 despite appropriate treatment with NSAIDs (and/or csDMARDs for peripheral spondyloarthritis) warrants treatment escalation to therapies such as adalimumab.
- While laboratory investigations can be used to support the diagnosis and assessment of disease activity in childhood ERA, there are significant limitations:
 - HLA-B27 is associated with ERA, but is not present in up to 50% of patients.
 - Inflammatory markers (e.g. erythrocyte sedimentation rate (ESR) and serum c-reactive protein (CRP)) may be elevated in ERA but are normal in many patients.
- It has therefore been suggested that these are not included as mandatory criteria to access adalimumab through the PBS for this indication.
- While magnetic resonance imaging (MRI) is a key tool for diagnosing and assessing disease activity of ERA, imaging of children is challenging and normal paediatric bone marrow MRI signal and dynamic bone growth can be mistaken for pathological changes. While MRI should be a key criterion for accessing advanced therapies through the PBS, assessment and interpretation should be undertaken

by practitioners with experience in juvenile spondyloarthritis and ideally using validated measures.

- Intravenous contrast usually is not required to accurately diagnose inflammatory sacroiliitis.

13.4 Humira is TGA registered for the treatment of enthesitis-related arthritis in children, who have had an inadequate response to, or who are intolerant to, conventional therapy. The recommended dose is the same as that for JIA. Humira has not been studied in patients with enthesitis-related arthritis aged <6 years or any child <10 kg (Humira Product Information).

13.5 Advice received from a rheumatologist stated that while ankylosing spondylitis in itself does not exist in individuals <18 years, there is an equivalent disease in JIA (enthesitis-related JIA). Some of these patients eventually transition to a diagnosis of ankylosing spondylitis. Some patients may already be accessing adalimumab through the JIA listing. For ankylosing spondylitis, it was thought that most patients <18 years with ankylosing spondylitis would be using a bDMARD (adalimumab or etanercept).

13.6 One clinician suggested that children with enthesitis-related JIA may require dose and frequency escalation when using adalimumab. The Product Information for Humira provides the following recommended dose for enthesitis-related arthritis for children ≥2 years:

- 10 kg to <30 kg: 20 mg fortnightly
- ≥30 kg: 40 mg fortnightly.

There are no recommendations in the Product Information for increased dose or frequency for this indication.

13.7 When preparing proposed listing criteria for this indication for paediatric patients for consideration by the PBAC, further advice was requested from paediatric rheumatologists. The advice requested and response is provided in the table below.

Table 7: Advice requested from paediatric rheumatologists and response

Advice requested	Response
How is an adequate response defined for this patient group?	<ul style="list-style-type: none"> • There are no validated or proposed measures that define response or minimal clinically important differences in enthesitis/spondylitis related juvenile idiopathic arthritis. • Most contemporary trials in enthesitis related juvenile arthritis use the American College of Rheumatology (ACR) Pediatric 30 (Pedi 30) criteria to define improvement^{19,20,21} • ACR Pedi 30 is a composite measure of disease response that equates to a 30% overall improvement. It is designed for use in patients with peripheral arthritis and is not a helpful tool to detect improvement in patients who predominantly have axial disease. • We would propose that a 30% improvement on baseline Juvenile Spondyloarthritis Disease Activity Index score would be a reasonable definition of improvement that would be applicable to a heterogenous group (i.e. those with peripheral and/or axial disease).
The treatment break for adalimumab in the proposed listing aligns with the break in treatment between cycles for the adult ankylosing spondylitis listing. Advice requested on how paediatric patients are currently managed and whether this treatment break period is appropriate for paediatric patients.	Most patients with this subtype of arthritis are diagnosed in adolescence so would be over the age of 18 after a 5-year gap. It would be unusual to re-try adalimumab if it was not initially effective. The only reason to keep this would be if a patient failed to respond as they did not have a reassessment in the required time frame. Given the workforce constraints and challenges faced by priority groups (particularly rural) this could be an issue for some. It could potentially be excluded, or alternatively a shorter period such as two years could be considered to cater for this group.
Advice requested on how patients are currently accessing treatment after they turn 18 years of age, in particular, if they fail to demonstrate an adequate response to adalimumab.	<ul style="list-style-type: none"> • As there is no current pathway for young people to access biologic therapies through the PBS for enthesitis/spondylitis related JIA, these patients generally access these medications through private funding, pharmaceutical company compassionate access programs or through public hospital pharmacy budgets. On turning 18, some of these patients will meet criteria for ankylosing spondylitis or non-radiographic axial spondyloarthritis and in some instances are able to access biological therapies through these corresponding PBS pathways. Alternatively, they will continue to access them through non-PBS means as listed above. • It would be unusual to persist with adalimumab or re-try adalimumab treatment in the event of non-response given that there are alternative agents available.

13.8 The paediatric rheumatologists also suggested the following for consideration:

- The terms synovitis and active arthritis are interchangeable however active arthritis may be best for consistency.
- The term enthesitis / spondylitis related JIA was suggested to reflect contemporary classification criteria.²²
- The reference provided for the Juvenile Spondyloarthritis Disease Activity Index is suitable.²³
- A significant majority of patients accessing adalimumab for this indication would be over 30 kg and therefore suited to the 40 mg dose however there are likely to be some patients where the 20 mg dose is preferable. It was asked if a similar listing for the 20 mg dose had been considered.
- For the enthesitis/spondylitis listing a cap on the prerequisite methotrexate dose (i.e. methotrexate 15 mg per metre square (maximum 20 mg)) in line with the severe JIA listing was proposed.
- Asked if it would be reasonable to include a 'grandfathering' PBS listing given that potentially eligible patients may currently be accessing adalimumab through non-PBS means.

Chronic plaque psoriasis

13.9 The ACD stated that as there is no current PBS listing for adalimumab for paediatric patients with psoriasis, this creates barriers for these patients in accessing timely, quality, appropriate and effective care and treatment.

13.10 The ACD was of the view that having a PBS listing for adalimumab 20 mg/0.2 mL solution for injection pre-filled syringe for the treatment of severe chronic plaque psoriasis in children ≥ 4 years who have had inadequate response to or are inappropriate candidates for topical therapy and phototherapy would be beneficial and consistent with the TGA registered indications for adalimumab.

¹⁹ Brunner H.I., Foeldvari I., Alexeeva E., et al, 2023, 'Secukinumab in enthesitis-related arthritis and juvenile psoriatic arthritis: a randomised, double-blind, placebo-controlled, treatment withdrawal, phase 3 trial', *Ann Rheum Dis*, 82(1), pp.154-160.

²⁰ Horneff G., Foeldvari I., Minden K., et al, 2015, 'Efficacy and safety of etanercept in patients with the enthesitis-related arthritis category of juvenile idiopathic arthritis: results from a phase III randomized, double-blind study', *Arthritis Rheumatol* 67(8), pp.2240-2249.

²¹ Burgos-Vargas R., Tse S.M.L., Horneff G., et al, 2015, 'A Randomized, Double-Blind, Placebo-Controlled Multicenter Study of Adalimumab in Pediatric Patients With Enthesitis-Related Arthritis', *Arthritis Care Res (Hoboken)*, 67(11), pp.1503-1512.

²² Martini A., Ravelli A., Avcin T., et al, 2019, 'Toward New Classification Criteria for Juvenile Idiopathic Arthritis: First Steps, Pediatric Rheumatology International Trials Organization International Consensus', *J Rheumatol* 46(2), pp.190-197.

²³ Weiss P.F., Colbert R.A., Xiao R., et al, 2014, 'Development and retrospective validation of the juvenile spondyloarthritis disease activity index', *Arthritis Care Res (Hoboken)*, 66(12), pp.1775-1782.

- 13.11 The ACD also noted that pustular psoriasis is a severe, life-threatening condition where urgent medical treatment with a biologic is required and cannot wait, and therefore considered that the requirement to need to fail two previous therapies to access treatment with adalimumab through the PBS is not appropriate. Humira is not TGA-registered for the treatment of pustular psoriasis.
- 13.12 Further advice was requested from the ACD regarding what constituted topical therapy in this situation, and for what duration topical therapy would be used before the patient was deemed to have an inadequate response to this treatment and consideration would be given to using adalimumab. The ACD advised a topical therapy referred to daily topical therapy of medium to high potency topical corticosteroids (+/- calcipotriol), or topical calcineurin inhibitor, for a duration of at least 28 days.
- 13.13 When preparing the proposed revised listings for this indication for consideration by the PBAC, further advice was requested from the ACD. A summary of advice requested from the ACD, and its response, is below:

Table 8: Advice requested from the ACD and response

Advice requested	ACD's response
<p>What proportion of paediatric patients diagnosed with chronic plaque psoriasis would likely be prescribed a 20 mg dose of adalimumab?</p>	<p>Studies suggest 1-20% of patients with paediatric psoriasis required systemic treatment (not specific for adalimumab), although the ACD noted this was based on data from European trials²⁴, and suggested 10% may be a more appropriate estimate. The 20 mg dose depends on the severity of the chronic plaque psoriasis and the child's weight.²⁵ Candidates for systemic therapy are patients who meet at least one of the following criteria³:</p> <ul style="list-style-type: none"> Body Surface Area (BSA) >10% Psoriasis Area and Severity Index (PASI) score >10 Physician's Global Assessment (PGA) >2 (scale 0-4) Disease involving specific high impact areas Severe pruritus leading to excoriation Dermatology Life Quality Index (DLQI) >10.
<p>What is the current treatment pathway for this patient group, including once they become adults (over 18 years of age)?</p>	<p>Topical therapy is first line, including corticosteroids, calcineurin inhibitors or vitamin D analogues. Phototherapy is commonly used in combination with topical agents.</p> <p>Systemic therapy is decided on baseline disease severity, disease activity, response to topical and phototherapy, and presence of comorbidities. Includes biologics (adalimumab, methotrexate, etanercept, etc).</p> <p>Psoriasis can be classified quantitatively using a combination of BSA, PASI, DLQI metrics. An age appropriate scale is needed when assessing paediatric patients. During treatment induction, the initial response should be assessed up to 16 weeks after therapy initiation or up to 24 weeks for therapies with a slower onset of action.</p> <p>Long term efficacy and safety of adalimumab in paediatric patients has been assessed in the literature for up to 52 weeks. As adults, the adalimumab dosage should be reviewed based on disease severity, comorbidities, patient conditions, previous response to therapy, and any adverse reactions. Once >18 years, patients would be eligible for other biologic therapies, and may change to an alternate biologic if their response to adalimumab was suboptimal.</p>
<p>Is the ACD able to provide any references (clinical papers, clinical/consensus guidelines) to support the request for the adalimumab 20 mg pre-filled syringe?</p>	<p>The response referred to the Consensus adaptation: Treatment goals for moderate-to-severe psoriasis in paediatric and adult Australian patients²⁶, and Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Considerations for paediatric patients²⁷, to supplement their advice.</p>
<p>Would the following definition for a failure to achieve an adequate response to prior therapy remain appropriate for this patient group?</p>	<p>This definition is appropriate for assessing inadequate response to prior therapy. However, there should be consideration for extending the 30% threshold to include genital area alongside, face, hands and feet, as paediatric</p>

Advice requested	ACD's response
<p>(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or</p> <p>(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy.</p>	<p>psoriasis often affects this area and causes significant distress.</p> <p>(When drafting the PBS listing it was noted that the definition of failure to achieve an adequate response to therapy for whole of body chronic plaque psoriasis for existing bDMARDs for this indication was not accounted for. The definition of an inadequate response to prior therapy for adalimumab has been drafted to be consistent with the current PBS listings for other bDMARDs for this indication.)</p>

13.14 Humira is TGA registered for the treatment of severe chronic plaque psoriasis in children and adolescent patients from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. Doses are administered subcutaneously weekly for the first two doses and fortnightly thereafter:

- <40 kg: 20 mg fortnightly (20 mg pre-filled syringe)
- ≥40 kg: 40 mg fortnightly (40 mg pen or 40 mg pre-filled syringe)

13.15 There is limited data on the efficacy or safety of the use of Humira for paediatric plaque psoriasis beyond 52 weeks.

Crohn disease and Moderate to severe ulcerative colitis

13.16 GESA noted that paediatric patients with inflammatory bowel disease have less access to advanced therapies through the PBS compared to adult patients, however, generally experience more severe disease and a higher inflammatory burden.

13.17 CCA and GESA were consistent with the following advice:

- Many paediatric patients with Crohn disease require dose escalation for adalimumab. However, this is not currently available on the PBS, meaning patients and clinicians are dependent on pharmaceutical companies to provide compassionate access to medications. CCA cited an Israeli study finding that 87% of paediatric patients with Crohn disease required dose escalation to reach

²⁴ Di Lernia V., Macca L., Peterle L., et al, 2022, 'Efficacy of Systemic Biologic Drugs in Pediatric Psoriasis: Evidence From Five Selected Randomized Clinical Trials', *Frontiers in Pharmacology*, 13, p.847308.

²⁵ TGA. Australian Public Assessment Report for Adalimumab. 2017. Available from: www.tga.gov.au/sites/default/files/auspar-adalimumab-170320.pdf

²⁶ www.dermcoll.edu.au/wp-content/uploads/2024/05/ACD-Consensus-Adaptation-Psoriasis-May-2024.pdf

²⁷ Foley P., Mahar P.D., Smith S.D., et al, 2024, 'Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies - Considerations for paediatric patients', *Australas J Dermatol*, 65:6, pp. e134-e144.

remission.²⁸ GESA also noted that with the use of adalimumab, evidence demonstrated that patients should receive earlier treatment with flexible dosing.

- CCA and GESA stated that the current Authority requirements for Humira for paediatric inflammatory bowel disease requires significant time by clinicians to complete the administrative tasks, thereby reducing time spent providing patient care. Both organisations requested that the initial application process remain unchanged, however subsequent treatment be available as Streamline Authority listings with the ability to make subsequent adjustments to dosing. The pre-PBAC response stated there are workforce shortages in paediatric specialties, and claimed that changing the continuing treatment listings for adalimumab for paediatric conditions to be Authority Required (STREAMLINED) listings would help optimise efficiencies within the healthcare system and reduce pressures on the healthcare workforce.

13.18 CCA requested that the current dosing limits for adalimumab be removed and more flexible dosing options be included in the PBS restrictions.

13.19 Advice received from one gastroenterologist stated that evidence suggests that paediatric patients with inflammatory bowel diseases should receive earlier treatment with adalimumab and have flexible dosing options. The gastroenterologist also raised concerns about the administrative burden currently associated with prescribing Humira for paediatric patients with inflammatory bowel disease.

13.20 One gastroenterologist noted that:

- paediatric patients with Crohn disease often have small intestinal disease, however there is no criteria on the PBS to account for this (unlike the listings for adult patients), which makes it difficult for children with severe small intestinal disease to meet the current criteria.
- the dose and frequency of adalimumab for paediatric inflammatory bowel disease are capped by the current PBS listings to fortnightly dosing at a maximum maintenance dose of 40 mg. Evidence shows that drug escalation and maintenance of response with therapeutic drug monitoring supports better remission.

It was also requested that age restrictions be removed. Humira is only indicated for Crohn disease in children ≥ 6 years.

13.21 When preparing the proposed revised listings for these indications for consideration by the PBAC, further advice was requested from CCA and GESA:

²⁸ Assa A, Matar M, Turner D, et al. (2019), 'Proactive monitoring of adalimumab trough concentration associated with increased clinical remission in children with Crohn's disease compared with reactive monitoring', *Gastroenterology*, 157:pp.985-96.

- For the management of ulcerative colitis and Crohn disease, what is the most commonly prescribed dose escalations regimens recommended in paediatric guidelines, and what proportion of paediatric patients would require dose escalations above what is currently included in the PBS listings for adalimumab for these indications?
- Advice on the clinical criteria for Crohn disease to accommodate children with small intestinal disease.

13.22 CCA stated that weekly dosing is the most common dose escalation regimen used for both ulcerative colitis and Crohn disease, using international treat to target guidelines.^{29,30,31} GESA stated that almost one quarter of patients will not respond to medication (primary non-response). GESA and the CCA stated that approximately half of patients will require weekly dose escalation, although acknowledged there are no published Australian studies on the proportion of patients requiring escalated dosing.³² CCA commented that at a tertiary inflammatory bowel disease service (which therefore had a 'sicker' group of patients), 9 out of 19 patients on adalimumab for inflammatory bowel disease had weekly dosing. It also provided an international reference investigating a treat-to-target approach, which found with the strictest criteria 60-80% of patients had dose escalation in the trial.⁵

13.23 GESA and CCA agreed the following criterion was appropriate:

Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application; or

²⁹ Turner D., Ricciuto A., Lewis A., et al, 2021, 'STRIDE-II: An Update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): Determining Therapeutic Goals for Treat-to-Target strategies in IBD. *Gastroenterology*, *160*(5), pp.1570-83. doi: 10.1053/j.gastro.2020.12.031. Epub 2021 Feb 19. PMID: 33359090.

³⁰ van Rheenen P.F., Aloï M., Assa A., et al, 2021, 'The Medical Management of Paediatric Crohn's Disease: An ECCO-ESPGHAN Guideline Update', *J Crohns Colitis*. *15*(2):171-194. doi: <https://doi.org/10.1093/ecco-jcc/jjaa161>

³¹ Turner D., Ruemmele F.M., Orlanski-Meyer E., et al, 2020, 2018, 'Management of Paediatric Ulcerative Colitis, Part 1: Ambulatory Care-An Evidence-based Guideline From European Crohn's and Colitis Organization and European Society of Paediatric Gastroenterology, Hepatology and Nutrition', *J Pediatr Gastroenterol Nutr*, *67*(2), pp.257-291. doi: 10.1097/MPG.0000000000002035. Erratum in: *J Pediatr Gastroenterol Nutr*, 2020, *71*(6), p.794. doi: 10.1097/MPG.0000000000002967. PMID: 30044357.

³² Dubinsky M.C., Rosh J., Faubion Jr W.A., et al, 2016, 'Efficacy and Safety of Escalation of Adalimumab Therapy to Weekly Dosing in Pediatric Patients with Crohn's Disease', *Inflamm Bowel Dis*, *22*:4, pp.886–893. doi: <https://doi.org/10.1097/MIB.0000000000000715>.

CCA commented it would prefer objective markers are used (such as in the Prescribing instructions below).

- 13.24 The below criteria is based on the current adult listing for adalimumab for severe Crohn disease:

Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Prescribing Instruction

For patients assessed as having extensive intestinal inflammation, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

GESA and CCA stated that this criterion was not relevant. GESA noted that a patient can have 50 cm of small intestine inflammation with no growth consequence, or have 10 cm of distal small intestine inflammation (ileal stricture) in children, which may impair linear growth. CCA suggested the 50 cm was not an appropriate measure for children who are growing. GESA and the CCA advised it would be more appropriate to use objective signs of inflammation as indicated in the Prescribing instructions, such as higher CRP 15, calprotectin, endoscopic disease activity and/or radiological evidence of inflammation in those not meeting PCDAI criteria as supporting evidence of inflammation. As CDAI is an adult score this should not be included for paediatric patients, and the Paediatric Crohn's Disease Activity Index (PCDAI) should be used instead.

CCA suggested this criterion could refer to 'extensive intestinal inflammation' only.

- 13.25 GESA and CCA were also asked what proportion of children diagnosed with Crohn disease would have extensive small intestinal disease and clinicians would consider treatment with adalimumab. CCA stated that extensive small bowel disease is an unusual phenotype of Crohn disease overall (including in paediatric patients), and the patient numbers are smaller. This form of Crohn disease is broadly defined as the L4b

phenotype according to the Paris classification of paediatric Crohn disease.³³ CCA noted that the number of patients is difficult to specify, but based on six separate cohorts 0-3% of patients have isolated extensive bowel disease. Up to 20% of patients have a degree of proximal small bowel inflammation associated with their other Crohn disease locations.^{34,35}

- 13.26 CCA estimated that all paediatric patients who would qualify for advanced therapies due to the extensive small bowel disease rule currently would also qualify under the PCDAI rule. These paediatric patients are particularly high risk and are usually commenced on infliximab. It estimated the number of paediatric patients with extensive bowel disease who would require adalimumab would be in the single digits per annum across Australia.

Moderate to severe hidradenitis suppurativa

- 13.27 The ACD considered there was no need to amend the listings for adalimumab for moderate to severe hidradenitis suppurativa. Currently there are PBS listings for adalimumab 80 mg (in both the pre-filled pen and pre-filled syringe) for patients ≥12 years who have had an inadequate response to conventional systemic therapy.

Severe active juvenile idiopathic arthritis

- 13.28 The ARA provided the following advice regarding the use of adalimumab for severe active JIA:
- The PBS criteria for adalimumab for JIA have not been updated to reflect the major advances in the management of this condition.
 - Contemporary treatment protocols recommend a treat to target strategy, with the goal of clinically inactive disease, and aims to control signs and symptoms; prevent structural damage; avoid comorbid conditions and drug toxicities; and optimise function, growth and development, quality of life and social participation.
 - Using DMARDs earlier and a treat to target strategy improves outcomes, including better response to therapy and improved functional status and wellbeing, reduces

³³ Levine A., Koletzko S., Turner D., et al, 2014, 'ESPGHAN revised porto criteria for the diagnosis of inflammatory bowel disease in children and adolescents', J Pediatr Gastroenterol Nutr. 58(6), pp.795-806.

³⁴ Kim H.J., Oh S.H., Kim D.Y., et al, 2017, 'Clinical Characteristics and Long-Term Outcomes of Paediatric Crohn's Disease: A Single-Centre Experience.', 11(2), pp.157-164.

³⁵ Eszter Müller K., Laszlo Lakatos P., Papp M., et al, 2014, 'Incidence and paris classification of pediatric inflammatory bowel disease', Gastroenterol Res Pract, 2014:904307. Corrigendum in Gastroenterol Res Pract. 2015;2015:804318.

the risk of permanent joint damage and arthroplasty, and improves the likelihood of long-term drug-free remission.

13.29 The ARA proposed the following changes to the PBS criteria for adalimumab for JIA to align with use in other countries such as the United Kingdom:

- Reduce the required oral or parenteral methotrexate dose from 20 mg/m² to 15 mg/m².
- Revise the definition of treatment failure to:
 - An active joint count of at least 10 active joints; OR
 - An active joint count of at least 2 affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; OR
 - Active synovitis affecting the cervical spine or a temporomandibular joint; OR
 - 2 or more separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; OR
 - Development or worsening of erosive disease due to ongoing synovitis.

13.30 When preparing the proposed revised listings for this indication for consideration by the PBAC, further advice was requested from paediatric rheumatologists on how an adequate response to adalimumab should be defined, taking into consideration the proposed revised criteria below for a failure to achieve an adequate response to prior treatment (that patients must demonstrate at the time of the initial application for adalimumab). Clinicians advised that, similar to advice for enthesitis or spondylitis related to JIA above, most clinical trials in JIA use ACR 30 Pedi criteria (equating to 30% global improvement) as the primary definition of response and this determination is usually assessed following 3-4 months of treatment. Treat to target recommendations suggest aiming for 50% improvement by 3 months of treatment.³⁶ Given the varied criteria for entry and difficulties with defining response for some of these, a 50% improvement was proposed as a good response (a reduction in joint count or the signs and symptoms attributable to active arthritis by 50% from the baseline measure used).

Proposed revised criteria for a failure to achieve adequate response to prior treatment

- (a) an active joint count of at least 10 active (swollen and tender) joints; OR
- (b) an active joint count of at least 2 affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; OR

³⁶ Ravelli A., Consolaro A., Horneff G., et al, 2018, 'Treating juvenile idiopathic arthritis to target: recommendations of an international task force', *Ann Rheum Dis* 77(6), pp.819-828.

- (c) active synovitis affecting the cervical spine or temporomandibular joint; OR
- (d) 2 or more separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; OR
- (e) development/worsening of erosive disease due to ongoing synovitis.

- 13.31 Further advice was also requested from the paediatric rheumatologists on suggested wording to define an adequate response in the proposed revised listings. The clinician advised that there is poor consensus on the best tool to use to determine response in juvenile arthritis.³⁷ A more global assessment of 50% improvement (either by active joint count OR signs/symptoms attributed to active arthritis) was suggested by the ARA for the response criteria, given the challenges with assessing and defining binary outcomes (improved vs not-improved) for some scenarios of individual 'inadequate response' definitions. The ARA were of the view that this provided an appropriate threshold for improvement that allows a relatively global assessment of the clinical situation while also maintaining a high bar for defining improvement in difficult to treat joints.
- 13.32 Advice was requested on how a change in certain Prescribing instructions criteria would be assessed in practice. A summary of the advice is provided below.

³⁷ Consolaro A., Giancane G., Schiappapietra B., et al, 2016, 'Clinical outcome measures in juvenile idiopathic arthritis', *Paediatr Rheumatol Online J* 14(1), p.23.

Table 9: Advice requested on assessing a change in criteria and advice provided

Criteria to assess a change	Advice provided on how a change is assessed for this criteria
Active arthritis affecting the cervical spine or temporomandibular joint	<p>Some patients will have a very clear improvement with complete resolution of joint pain and joint restriction. In these cases response can be confidently determined. Other patients will have no clinical improvement at all (also easy to determine).</p> <p>In some cases, the response may not be as clear, as we are unable to assess for the presence of swelling in these joints and they are prone to damage (temporomandibular condylar flattening/hypoplasia, cervical spine ankylosis, cervical disc hypoplasia) which can affect assessment of other parameters such as pain and range of motion. In such scenarios, serial imaging, generally with MRI, can be helpful to understand response to treatment.³⁸</p> <p>The following definition for adequate response was proposed: an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint.</p>
Development/worsening of erosive disease due to active arthritis	<p>This would first involve careful longitudinal clinical assessment to ensure that active arthritis is managed adequately. As per the cervical spine and temporomandibular joint, this may be very evident clinically, however, we would have a low threshold to image joint with erosive change to ensure there is adequate disease control to mitigate the risk of progressive damage.</p> <p>The following definition for adequate response was proposed: an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting a joint with existing erosive disease.</p>

13.33 The clinician suggested the use of clinical juvenile arthritis disease activity score (cJADAS) could be considered if a more specific measure of change is required. It was noted that while this is not routinely used in clinical practice, it could be used for the purposes of assessing and documenting response for PBS prescriptions. The clinician stated it is a composite measure that considers physician global assessment of overall disease activity, patient global assessment of wellbeing and active joint count.³⁹ However, the clinician recommended against using as it has not been evaluated in this context and may not accurately determine clinically important response.

13.34 The clinician believed that, with the scenarios in Table 9, the likelihood of misuse by using an ineffective therapy is low as the cervical spine, temporomandibular joints and joints with erosive disease are critical joints that will be treated comprehensively. The clinician also considered that complete resolution of active arthritis in a joint with erosive changes after 16 weeks of treatment is too aspirational as they are difficult to treat joints and may take longer to respond.

For more detail on PBAC’s view, see section 16 PBAC outcome.

³⁸ Stoll M.L., Kau C.H., Waite P.D., et al, 2018, ‘Temporomandibular joint arthritis in juvenile idiopathic arthritis, now what?’, *Pediatr Rheumatol Online J* 16(1), p.32.

³⁹ Consolaro, A., Negro, G., Chiara Gallo, M., et al, 2014, ‘Defining Criteria for Disease Activity States in Nonsystemic Juvenile Idiopathic Arthritis Based on a Three-Variable Juvenile Arthritis Disease Activity Score’, *Arthritis Care Res (Hoboken)*, 66(11), pp.1703-1709.

14 Proposed listings

- 14.1 The pre-PBAC response stated that the proposed listings included the requirement to demonstrate an inadequate response or intolerance to conventional systemic therapy, and claimed that patients with the most severe disease will have delayed access to a potentially beneficial bDMARD for their condition. It claimed there were potential benefits of early, aggressive treat-to-target approaches in particularly severe patients, and delaying treatment risks irreversible joint, bowel, and psychological impact
- 14.2 Based on clinical advice received, the following new and revised listings for Humira for paediatric IMIDs were proposed (suggestions and additions proposed by the Secretariat are added in **italics** and suggested deletions are crossed out with **strikethrough**):

Add new indications to adalimumab as follows:

Amend existing listings/add new restrictions as follows:

New listing - Chronic plaque psoriasis

MEDICINAL PRODUCT <i>medicinal product pack</i>	PBS <i>item code</i>	Max. <i>qty packs</i>	Max. <i>qty units</i>	No. of <i>Rpts</i>	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>4</i>	<i>Humira</i>
<i>adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>4</i>	<i>Humira</i>
<i>adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>4</i>	<i>Humira</i>
Category / Program: <input checked="" type="checkbox"/> <i>GENERAL - General Schedule (Code GE)</i>					
Prescriber type: <input checked="" type="checkbox"/> <i>Medical Practitioners</i>					
Restriction type: <input checked="" type="checkbox"/> <i>Authority Required (in writing only via post/HPOS upload)</i>					
Administrative Advice: <i>Special Pricing Arrangements apply.</i>					
Administrative Advice: <i>No increase in the maximum number of repeats may be authorised.</i>					
Administrative Advice: <i>No increase in the maximum quantity or number of units may be authorised.</i>					
Administrative Advice: <i>Where the term a 'biological medicine' appears in this restriction, it refers to (i) adalimumab, (ii) etanercept, and (iii) ustekinumab.</i>					
Administrative Advice: <i>Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</i>					
<i>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</i>					

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<p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
Indication: Severe chronic plaque psoriasis
Treatment Phase: Initial treatment (Whole body)
Treatment criteria:
Must be treated by a dermatologist
Clinical criteria:
Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis
AND
Clinical criteria:
Patient must not have received PBS-subsidised treatment with a biological medicine for this condition
AND
Clinical criteria:
Patient must have failed to achieve an adequate response following both: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) daily topical therapy for at least 4 weeks; or
Patient must be an inappropriate candidate for both: (i) phototherapy, (ii) topical therapy
AND
Clinical criteria:
Patient must not receive more than 17 weeks of treatment under this restriction
Population criteria:
Patient must be 4-17 years inclusive
Prescribing Instructions:
The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) The most recent PASI assessment must be no more than 1 month old at the time of application.
Prescribing Instructions:
The authority application must be made in writing and must include:
(a) details of the proposed prescription(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and topical drug therapy [dosage (where applicable), date of commencement and duration of therapy], or details of why the patient was inappropriate candidate for those treatments.
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)

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Indication: Severe chronic plaque psoriasis
Treatment Phase: Initial treatment (Face, hand, foot)
Treatment criteria:
Must be treated by a dermatologist
Clinical criteria:
Patient must have severe chronic plaque psoriasis of the face, or palm of a hand, or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis
AND
Clinical criteria:
Patient must not have received PBS-subsidised treatment with a biological medicine for this condition
AND
Clinical criteria:
Patient must have failed to achieve an adequate response following both: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) daily topical therapy for at least 4 weeks
Patient must be an inappropriate candidate for both: (i) phototherapy, (ii) topical therapy;
AND
Clinical criteria:
Patient must not receive more than 17 weeks of treatment under this restriction
Population criteria:
Patient must be 4-17 years inclusive
Prescribing Instructions:
The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand, or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand, or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;
(b) The most recent PASI assessment must be no more than 1 month old at the time of application.
Prescribing Instructions:
The authority application must be made in writing and must include:
(a) details of the proposed prescription(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot diagrams including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and topical drug therapy [dosage (where applicable), date of commencement and duration of therapy] or details of why the patient was inappropriate candidate for those treatments.
Prescribing Instructions:
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					

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adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe	NEW	2	2	5	Humira
adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices	NEW	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Administrative Advice: Special Pricing Arrangements apply.					
Administrative Advice: No increase in the maximum number of repeats may be authorised.					
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: First continuing treatment, Whole body					
Treatment criteria: Must be treated by a dermatologist					
Clinical criteria: Patient must have received PBS-subsidised treatment with this drug for this condition					
AND					
Clinical criteria: Patient must have demonstrated an adequate response to treatment with this drug					
AND					
Clinical criteria:					

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<i>Patient must not receive more than 24 weeks of treatment under this restriction</i>
<p>Prescribing Instructions: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value.</p>
<p>Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>
<p>Prescribing Instructions: The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.</p>
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
Indication: Severe chronic plaque psoriasis
Treatment Phase: First continuing treatment (Face, hand, foot)
Treatment criteria: Must be treated by a dermatologist
Clinical criteria: Patient must have received PBS-subsidised treatment with this drug for this condition
AND
Clinical criteria: Patient must have demonstrated an adequate response to treatment with this drug
AND
Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction
<p>Prescribing Instructions: An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value.</p>
<p>Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>

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<p>Prescribing Instructions: The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)</p>
<p>Indication: Severe chronic plaque psoriasis</p>
<p>Treatment Phase: Subsequent continuing treatment (Whole body)</p>
<p>Treatment criteria: Must be treated by a dermatologist</p>
<p>Clinical criteria: Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction</p>
<p>AND</p>
<p>Clinical criteria: Patient must have demonstrated an adequate response to treatment with this drug</p>
<p>AND</p>
<p>Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction</p>
<p>Prescribing Instructions: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value.</p>
<p>Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>
<p>Prescribing Instructions: The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)</p>
<p>Indication: Severe chronic plaque psoriasis</p>
<p>Treatment Phase: Subsequent continuing treatment (Face, hand, foot)</p>

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Treatment criteria:
<i>Must be treated by a dermatologist</i>
Clinical criteria:
<i>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction</i>
AND
Clinical criteria:
<i>Patient must have demonstrated an adequate response to treatment with this drug</i>
AND
Clinical criteria:
<i>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction</i>
Prescribing Instructions:
<i>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value.</i>
Prescribing Instructions:
<i>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</i>
Prescribing Instructions:
<i>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</i>
Prescribing Instructions:
<i>The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.</i>

Summary of matters for the PBAC

14.3 The proposed restrictions were adapted based on suggestions from the ACD and the existing listings of bDMARDs for the treatment of paediatric chronic plaque psoriasis. The definition of an inadequate response to prior therapy for adalimumab was drafted to be consistent with current PBS listing for other bDMARDs for this indication. This differs from the advice received from the ACD, as outlined in Table 8.

Change to existing listing - Moderate to severe ulcerative colitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12347W	3	6	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12359L	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12382Q	3	6	0	Humira

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adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12374G	3	3	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe	12339K	3	3	0	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12371D	1	2	3	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
<p>Administrative Advice: TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS</p> <p>The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.</p> <p>Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.</p> <p>Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.</p> <p>From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.</p> <p>A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.</p> <p>A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.</p> <p>Selecting the correct treatment phase listing when applying for authority approval:</p> <p>(1) Initial treatment.</p> <p>Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.</p> <p>(2) Continuing treatment.</p> <p>Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.</p>					

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Administrative Advice:

TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Re commencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Re commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the

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<p>maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.</p> <p>(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.</p> <p>A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.</p>
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Indication: Moderate to severe ulcerative colitis
Treatment Phase: Initial treatment - Initial 1 (new patient)
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Clinical criteria:
Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal
AND
Clinical criteria:
Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or
Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or
Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent
AND
Clinical criteria:
Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or
Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or
Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years
Population criteria:
Patient must be 6 years of age or older

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<p>Prescribing Instructions: The authority application must be made in writing and must include:</p> <p>(1) <i>details of the proposed two-completed-authority</i> prescription(s) forms; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p>
<p>Prescribing Instructions: All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p>
<p>Prescribing Instructions: The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.</p>
<p>Prescribing Instructions: A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p>
<p>Prescribing Instructions: The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p>
<p>Prescribing Instructions: If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p>
<p>Prescribing Instructions: An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p>
<p>Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>
<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>
<p>Prescribing Instructions: Details of the accepted toxicities including severity can be found on the Services Australia website.</p>

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Administrative Advice:

~~Details of two completed authority prescriptions should be submitted with every initial application for this biological medicine.~~

Prescribing the 40 mg presentation:

~~For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.~~

~~For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.~~

Prescribing the 80 mg presentation:

~~For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.~~

~~For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.~~

Administrative Advice:

~~A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.~~

Administrative Advice:

~~At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction (inclusive of loading doses).~~

Administrative Advice:

At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

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<p>Administrative Advice:</p> <p>Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to:</p> <p>Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)</p>
<p>Indication: Moderate to severe ulcerative colitis</p>
<p>Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p>
<p>Treatment criteria:</p>
<p>Must be treated by a gastroenterologist (code 87); or</p>
<p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>
<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or</p>
<p>Must be treated by a paediatrician; or</p>
<p>Must be treated by a specialist paediatric gastroenterologist</p>
<p>Clinical criteria:</p>
<p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; or</p>
<p>Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years</p>
<p>AND</p>
<p>Clinical criteria:</p>
<p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; or</p>
<p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years</p>
<p>Population criteria:</p>
<p>Patient must be 6 years of age or older</p>

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Prescribing Instructions:

The authority application must be made in writing and must include:

- (1) *details of the proposed ~~two completed authority~~ prescription(s) forms*; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
 - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
 - (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

Prescribing Instructions:

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Prescribing Instructions:

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Prescribing Instructions: A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

Prescribing Instructions: If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Administrative Advice:

~~Details of two completed authority prescriptions should be submitted with every initial application for this biological medicine.~~

Prescribing the 40 mg presentation:

~~For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.~~

~~For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.~~

Prescribing the 80 mg presentation:

~~For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.~~

~~For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.~~

Administrative Advice:

~~A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.~~

Administrative Advice:

~~At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction (inclusive of loading doses).~~

Administrative Advice:

*At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.
An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.*

Administrative Advice:

Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. **EST** Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826

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HOBART TAS 7001
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
Indication: Moderate to severe ulcerative colitis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition
AND
Clinical criteria:
Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition
AND
Clinical criteria:
Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or
Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or
Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years
Population criteria:
Patient must be 6 years of age or older
Prescribing Instructions: The authority application must be made in writing and must include:
(1) <i>details of the proposed</i> two completed authority -prescription(s) forms; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.
Prescribing Instructions: All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.
Prescribing Instructions: The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

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<p>Prescribing Instructions: A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p>
<p>Prescribing Instructions: To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p>
<p>Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>
<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>
<p>Prescribing Instructions: Details of the accepted toxicities including severity can be found on the Services Australia website.</p>
<p>Administrative Advice:</p> <p>Details of two completed authority prescriptions should be submitted with every initial application for this biological medicine.</p> <p>Prescribing the 40 mg presentation:</p> <p>For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.</p> <p>For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.</p> <p>Prescribing the 80 mg presentation:</p> <p>For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.</p> <p>For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.</p>
<p>Administrative Advice:</p> <p>A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.</p>
<p>Administrative Advice: <i>At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment. An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.</i></p>

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Administrative Advice:					
Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).					
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au					
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos					
Or mailed to:					
Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12347W	3	6	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12412G	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12359L	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12382Q	3	6	0	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12371D	1	2	3	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Administrative Advice: As above					
Administrative Advice: As above					
Administrative Advice: As above					
Administrative Advice: As above					
Administrative Advice: As above					
Indication: Moderate to severe ulcerative colitis					

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Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Clinical criteria:
Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or
Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or
Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment
AND
Clinical criteria:
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12337H	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12358K	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12391E	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Administrative Advice: As above					
Administrative Advice: As above					
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).					

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Administrative Advice: No increase in the maximum number of repeats may be authorised.
Indication: Moderate to severe ulcerative colitis
Treatment Phase: First continuing treatment
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition
AND
Clinical criteria:
Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or
Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years
Population criteria:
Patient must be 6 years of age or older
Prescribing Instructions: Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.
Prescribing Instructions: Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.
Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.
Prescribing Instructions: Where fewer than 5 repeats are requested at the time of the application, Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction <i>for patients who:</i> <i>(i) received fewer than 5 repeats at the time of application; and/or</i> <i>(ii) required changes to their dosing regimen during this treatment phase.</i>
Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>
<p>Prescribing Instructions: A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>
<p>Prescribing Instructions: If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)</p>
<p>Indication: Moderate to severe ulcerative colitis</p>
<p>Treatment Phase: Continuing treatment - balance of supply</p>
<p>Treatment criteria:</p>
<p>Must be treated by a gastroenterologist (code 87); or</p>
<p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>
<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or</p>
<p>Must be treated by a paediatrician; or</p>
<p>Must be treated by a specialist paediatric gastroenterologist</p>
<p>Clinical criteria:</p>
<p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment</p>
<p>AND</p>
<p>Clinical criteria:</p>
<p>The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)</p>
<p>Indication: Moderate to severe ulcerative colitis</p>
<p>Treatment Phase: Subsequent continuing treatment</p>
<p>Treatment criteria:</p>
<p>Must be treated by a gastroenterologist (code 87); or</p>
<p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>
<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or</p>
<p>Must be treated by a paediatrician; or</p>
<p>Must be treated by a specialist paediatric gastroenterologist</p>
<p>Clinical criteria:</p>
<p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction</p>
<p>AND</p>

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Clinical criteria:
Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or
Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years
Population criteria:
Patient must be 6 years of age or older
Prescribing Instructions: Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.
Prescribing Instructions: Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.
Prescribing Instructions: At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.
Prescribing Instructions: Where fewer than 5 repeats are requested at the time of the application, a Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction for patients who: <i>(i) received fewer than 5 repeats at the time of application; and/or</i> <i>(ii) required changes to their dosing regimen during this treatment phase.</i>
Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
Prescribing Instructions: A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.
Prescribing Instructions: If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Summary of changes and matters for PBAC consideration

14.4 Based on feedback from clinical groups and clinicians, proposed amendments to the current PBS listings for adalimumab for the treatment of moderate to severe ulcerative colitis, to allow for flexible dosing/dose escalation in the initial treatment phase were provided to the PBAC for consideration (dose escalations are already permitted for continuing therapy). The administrative advice in the initial therapy

listings were amended to remove specific reference to initial dosing and frequency. This change was made based on the assumption that specialist prescribers would likely want dosing flexibility at their discretion. Suggested amendments to the restriction were dosing agnostic. The duration of treatment remained capped at 16 weeks of therapy for initial treatment and 24 weeks of therapy for continuation treatment.

Change to existing listing - Severe Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12407B	1	2	3	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12373F	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12338J	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12432H	3	6	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12455M	3	6	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12426B	3	3	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe	12409D	3	3	0	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Administrative Advice: TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE					
<p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.</p> <p>A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.</p> <p>From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.</p> <p>A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.</p>					

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Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Administrative Advice:

~~Two completed authority prescriptions should be submitted with every initial application for this biological medicine.~~

Prescribing the 40 mg presentation:

~~For patients weighing at least 40 kg, one prescription should be for the induction doses, containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats.~~

~~For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.~~

Prescribing the 80 mg presentation:

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~~For patients weighing at least 40 kg, one prescription should be for the 80 mg presentation with a quantity of 3 units and zero repeats. This will enable doses at week 0 and week 2 to be completed. The second prescription should be written for 2 doses of 40 mg and 2 repeats.~~

~~For patients weighing less than 40 kg, one prescription should be written for 1 dose of 80 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.~~

~~Requests for quantities/repeats insufficient to complete 16 weeks:
If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be sought through the 'Balance of Supply' PBS restriction.~~

~~**Administrative Advice:**~~

~~A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) may be requested.~~

Administrative Advice:

At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

Administrative Advice:

Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Indication: Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence

AND

Clinical criteria:

Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; or

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Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate
AND
Clinical criteria:
Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application; <i>or</i>
<i>Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging;</i>
AND
Clinical criteria:
Patient must not receive more than 16 weeks of treatment under this restriction
Treatment criteria:
Must be treated by a gastroenterologist (code 87); <i>or</i>
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; <i>or</i>
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; <i>or</i>
Must be treated by a paediatrician; <i>or</i>
Must be treated by a specialist paediatric gastroenterologist
Population criteria:
Patient must be aged 6 to 17 years inclusive
Prescribing Instructions: The authority application must be made in writing and must include:
(1) <i>details of the proposed two completed authority prescription(s) forms;</i> and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
Prescribing Instructions: <i>For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:</i>
<i>(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</i>
<i>(ii) faeces: higher than normal lactoferrin or calprotectin level; or</i>
<i>(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</i>
Prescribing Instructions: If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).
Prescribing Instructions: An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.
Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
Indication: Severe Crohn disease
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)
Clinical criteria:
Patient must have a documented history of severe Crohn disease
AND
Clinical criteria:
Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle
AND
Clinical criteria:
Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle
AND
Clinical criteria:
Patient must not receive more than 16 weeks of treatment under this restriction
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Population criteria:
Patient must be aged 6 to 17 years inclusive
Prescribing Instructions: The authority application must be made in writing and must include:
(1) <i>details of the proposed</i> two completed authority prescription(s) forms; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
Prescribing Instructions: To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.
Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
Indication: Severe Crohn disease

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Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)
Clinical criteria:
Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition
AND
Clinical criteria:
Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition
AND
Clinical criteria:
Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist
AND
Clinical criteria:
Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; or
<i>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease that is no more than 4 weeks old at the time of application,</i>
AND
Clinical criteria:
Patient must not receive more than 16 weeks of treatment under this restriction
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Population criteria:
Patient must be aged 6 to 17 years inclusive
Prescribing Instructions: The authority application must be made in writing and must include:
(1) <i>details of the proposed</i> two completed authority prescription(s) forms; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
Prescribing Instructions: The PCDAI assessment must be no more than 4 weeks old at the time of application.
Prescribing Instructions: A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.
Prescribing Instructions: To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.
Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12423W	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12411F	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12379M	1	2	0	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Administrative Advice: As above					
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).					
Indication: Severe Crohn disease					
Treatment Phase: Balance of supply for paediatric patient					
Clinical criteria:					
Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or					
Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or					
Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or					
Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment					
AND					
Clinical criteria:					
The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; or					
The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment					
Treatment criteria:					
Must be treated by a gastroenterologist (code 87); or					
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or					
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or					
Must be treated by a paediatrician; or					
Must be treated by a specialist paediatric gastroenterologist					

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12424X	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12341M	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12413H	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> General Schedule					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (HPOS/online)					
Administrative Advice: As above					
Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001					
Indication: Severe Crohn disease					
Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI					
Clinical criteria: Patient must have a documented history of severe Crohn disease					
AND					
Clinical criteria: Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition					
AND					
Clinical criteria: Patient must have a reduction in PCDAI Score by at least 15 points from baseline value					
AND					
Clinical criteria: Patient must have <i>both: (i) a total PCDAI score of 40 points or less and (ii) a reduction in PCDAI Score by at least 15 points from baseline value; or</i>					

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<i>Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment</i>
AND
Clinical criteria:
Patient must not receive more than 24 weeks of treatment under this restriction
Population criteria:
Patient must be aged 6 to 17 years inclusive
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Prescribing Instructions: The authority application must be made in writing and must include:
(1) <i>details of the proposed</i> a-completed-authority <i>prescription(s) form; and</i>
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
Prescribing Instructions: The PCDAI assessment must be no more than 4 weeks old at the time of application.
Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Prescribing Instructions: Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.
Prescribing Instructions: Where fewer than 5 repeats are requested at the time of the application, aAuthority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply <i>restriction for patients who:</i> <i>(i) received fewer than 5 repeats at the time of application; and/or</i> <i>(ii) required changes to their dosing regimen during this treatment phase.</i>
Indication: Severe Crohn disease
Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI
Clinical criteria:
Patient must have a documented history of severe Crohn disease
AND
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction
AND

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Clinical criteria:
Patient must have a reduction in PCDAI Score by at least 15 points from baseline value
AND
Clinical criteria:
Patient must have <i>both: (i) a total PCDAI score of 40 points or less and (ii) a reduction in PCDAI Score by at least 15 points from baseline value; or</i>
<i>Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment</i>
AND
Clinical criteria:
Patient must not receive more than 24 weeks of treatment under this restriction
Population criteria:
Patient must be aged 6 to 17 years inclusive
Treatment criteria:
Must be treated by a gastroenterologist (code 87); or
Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or
Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or
Must be treated by a paediatrician; or
Must be treated by a specialist paediatric gastroenterologist
Prescribing Instructions: The authority application must be made in writing and must include:
(1) <i>details of the proposed a-completed-authority prescription(s) form; and</i>
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
Prescribing Instructions: The PCDAI assessment must be no more than 4 weeks old at the time of application.
Prescribing Instructions: An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Prescribing Instructions: Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.
Prescribing Instructions: Where fewer than 5 repeats are requested at the time of the application, Authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction <i>for patients who:</i>
<i>(i) received fewer than 5 repeats at the time of application; and/or</i>
<i>(ii) required changes to their dosing regimen during this treatment phase.</i>

Summary of changes and matters for PBAC consideration

14.5 Based on feedback from clinical groups and clinicians, proposed amendments to the current PBS listings for adalimumab for the treatment of severe Crohn disease, to

allow for flexible dosing/dose escalation, were provided to the PBAC for consideration. These were consistent with the proposed changes to the PBS listings for adalimumab for moderate to severe ulcerative colitis.

- 14.6 In addition, proposed amendments were made to the clinical criteria in the Initial therapy listings (Initial 1 - New patient and Initial 3 – Recommencement of therapy after a 5 year treatment break). These were proposed based on stakeholder feedback, to facilitate access to paediatric patients with Crohn disease who have extensive small intestinal inflammation. Clinical stakeholder input stated that the length of affected small bowel need not be specified and that the criteria should reflect objective markers only.
- 14.7 The proposed changes to the adalimumab listings for this condition are inconsistent with the current PBS listings for infliximab for severe Crohn disease.

Change to existing listing - Severe active juvenile idiopathic arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12406Y	1	2	0	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12443X	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12335F	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12444Y	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12431G	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12396K	1	2	0	Humira
Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)					
Administrative Advice:					
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS					
The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.					
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".					
Treatment cycles:					

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From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Grandfather patients (tofacitinib only).

A patient who commenced treatment with tofacitinib for severe active juvenile idiopathic arthritis prior to 1 December 2023 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

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A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(6) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(7) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Administrative Advice:

Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Indication: Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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Clinical criteria:
Patient must not have received PBS-subsidised treatment with a biological medicine for this condition
AND
Clinical criteria:
Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or
Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months
AND
Clinical criteria:
Patient must not receive more than 16 weeks of treatment under this restriction
AND
Treatment criteria:
Must be treated by a paediatric rheumatologist; or
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre
AND
Population criteria:
Patient must be under 18 years of age
Prescribing Instructions: Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.
Prescribing Instructions: Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.
Prescribing Instructions: If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.
Prescribing Instructions: If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.
Prescribing Instructions: The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
(a) an active joint count of at least 20 10 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; OR
(c) active arthritis affecting the cervical spine or temporomandibular joint; OR

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<p><i>(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; OR</i></p> <p><i>(e) development/worsening of erosive disease due to active arthritis.</i></p>
<p>The assessment of response to prior treatment must be documented in the patient's medical records.</p>
<p>Prescribing Instructions: The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p>
<p>Prescribing Instructions: The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p>
<p>Prescribing Instructions: At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p>
<p>Prescribing Instructions: The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p>
<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>
<p>Administrative Advice: Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.</p>
<p>Administrative Advice: Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au</p>
<p>Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)</p>
<p>Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)</p>
<p>Indication: Severe active juvenile idiopathic arthritis</p>
<p>Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)</p>
<p>Clinical criteria: Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle</p>
<p>AND</p>
<p>Clinical criteria:</p>

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Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle
AND
Clinical criteria:
Patient must not receive more than 16 weeks of treatment under this restriction
Treatment criteria:
Must be treated by a paediatric rheumatologist; or
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre
Prescribing Instructions: An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 10 active joints; or
(b) a reduction in the number of the following active joints, from at least 4 2, by at least 50%: <i>elbow, wrist, knee, ankle, shoulder, and hip</i> ; OR (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
<i>(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; OR</i>
<i>(d) a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; OR</i>
<i>(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.</i>
The assessment of response to treatment must be documented in the patient's medical records.
Prescribing Instructions: At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.
Prescribing Instructions: An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.
Prescribing Instructions: The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.
Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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<p>Prescribing Instructions: A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p>
<p>Prescribing Instructions: If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>
<p>Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)</p>
<p>Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)</p>
<p>Indication: Severe active juvenile idiopathic arthritis</p>
<p>Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)</p>
<p>Clinical criteria: Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition</p>
<p>AND</p>
<p>Clinical criteria: Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition</p>
<p>AND</p>
<p>Clinical criteria: The condition must have either: (a) a total active joint count of at least 2010 active (swollen and tender) joints; (b) at least 42 active major joints; (c) <i>active arthritis affecting the cervical spine or temporomandibular joint</i>; (d) <i>at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease</i>; (e) <i>development/worsening of erosive disease due to active arthritis</i></p>
<p>AND</p>
<p>Clinical criteria: Patient must not receive more than 16 weeks of treatment under this restriction</p>
<p>Treatment criteria: Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre</p>
<p>Prescribing Instructions: Active joints are defined as <i>elbow, wrist, knee, ankle, shoulder and hip</i>.</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p>

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<p>Prescribing Instructions: Where the baseline active joint count is based on total active joints (i.e. more than 20 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p>
<p>Prescribing Instructions: At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p>
<p>Prescribing Instructions: The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:</p> <p>(a) the date of assessment of severe active juvenile idiopathic <i>arthritis</i>; and</p> <p>(b) the date of the last continuing prescription.</p>
<p>Prescribing Instructions: An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p>
<p>Prescribing Instructions: The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p>
<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>
<p>Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)</p>
<p>Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)</p>
<p>Indication: Severe active juvenile idiopathic arthritis</p>
<p>Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply</p>
<p>Clinical criteria: Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or</p>
<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; or</p>
<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment</p>
<p>AND</p>
<p>Clinical criteria: The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions</p>

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Treatment criteria:
Must be treated by a paediatric rheumatologist; or
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	13292N	1	2	5	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	13293P	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13210G	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13229G	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13212J	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13228F	1	2	5	Humira

Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)
Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)
As above
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
As above
As above
As above
As above
Indication: Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment
Clinical criteria: Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition
AND
Clinical criteria: Patient must have demonstrated an adequate response to treatment with this drug
AND
Clinical criteria:

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Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction
Treatment criteria:
Must be treated by a rheumatologist; or
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre
Prescribing Instructions: An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 10 active joints; or
(b) a reduction in the number of the following active joints, from at least 4-2, by at least 50%: <i>elbow, wrist, knee, ankle, shoulder, and hip</i> ; or
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
<i>(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; OR</i>
<i>(d) a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; OR</i>
<i>(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.</i>
The assessment of response to treatment must be documented in the patient's medical records.
Prescribing Instructions: Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.
Prescribing Instructions: The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.
Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
Prescribing Instructions: A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.
Prescribing Instructions: If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Summary of changes and matters for PBAC consideration – JIA

14.8 Based on stakeholder input, proposed amendments were made to the PBS listings for adalimumab for severe active JIA for the PBAC to consider:

- The dose per metre square for prior oral or parenteral methotrexate was changed to 15 mg (down from 20 mg).
- The parameters in the definition of an inadequate response to prior DMARD therapy, and the corresponding definition of an adequate response to adalimumab, were amended. Proposed changes allowing for improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease, or active arthritis affecting the cervical spine or temporomandibular joint, introduce subjectivity into the assessment of response.

14.9 The pre-PBAC response requested the PBAC consider a Grandfather listing for JIA to account for patients with JIA who do not meet the current PBS criteria and are accessing adalimumab through private funding or compassionate supply, but who would meet the proposed new criteria, if recommended by the PBAC.

14.10 Proposed changes to the adalimumab listing are inconsistent with the current PBS listings for paediatric severe active JIA for etanercept, tocilizumab and tofacitinib. If there are different listings and criteria, patients may not be able to qualify for continuing therapy if switching between medicines, as the baseline parameters for disease severity are not aligned.

New listing - Enthesitis/spondylitis related juvenile idiopathic arthritis

MEDICINAL PRODUCT <i>medicinal product pack</i>	PBS <i>item code</i>	Max. <i>qty packs</i>	Max. <i>qty units</i>	No.of <i>Rpts</i>	Available brands
ADALIMUMAB					
<i>adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>Humira</i>
<i>adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>Humira</i>
<i>adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>Humira</i>
Category / Program: <input checked="" type="checkbox"/> <i>GENERAL - General Schedule (Code GE)</i>					
Prescriber type: <input checked="" type="checkbox"/> <i>Medical Practitioners</i>					
Restriction type: <input checked="" type="checkbox"/> <i>Authority Required (in writing only via post/HPOS upload)</i>					
Administrative Advice: <i>No increase in the maximum quantity or number of units may be authorised.</i>					
Administrative Advice: <i>No increase in the maximum number of repeats may be authorised.</i>					
Administrative Advice: <i>The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/.</i>					
Episodicity: <i>[blank]</i>					
Severity: <i>[blank]</i>					
Condition: <i>Enthesitis/spondylitis related juvenile idiopathic arthritis</i>					
Indication: <i>Enthesitis/spondylitis related juvenile idiopathic arthritis</i>					

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Treatment Phase: Initial treatment
Clinical criteria:
Patient must have a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative
AND
Clinical criteria:
Patient must not have received PBS-subsidised treatment with a biological medicine for this condition-; or
Patient must have had a break in treatment of at least 2 years from the most recently approved PBS-subsidised biological medicine for this condition.
AND
Clinical criteria:
Patient must have failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; or
Patient must have failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months
AND
Clinical criteria:
Patient must not receive more than 16 weeks of treatment under this restriction.
Treatment criteria:
Must be treated by a paediatric rheumatologist; or
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
Population criteria:
Patient must be under 18 years of age.
Prescribing Instructions:
The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.
If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.
If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.
Prescribing Instructions:
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or
(b) Persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

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<p>Prescribing Instructions: The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>
<p>Prescribing Instructions: The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(i) the baseline Juvenile Spondyloarthritis Disease Activity Index score;</p> <p>(ii) If applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the magnetic resonance imaging demonstrating inflammatory spondylitis or sacroiliitis; and</p> <p>(iii) If applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.</p>
<p>Prescribing Instructions: An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p>
<p>Prescribing Instructions: Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p>
<p>Prescribing Instructions: If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>
<p>Administrative Advice: Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au</p>
<p>Administrative Advice: For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au</p>
<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to:</p> <p>Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>

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Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Episodicity: [blank]					
Severity: [blank]					
Condition: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Initial treatment - balance of supply					
Clinical criteria:					
Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction to complete 16 weeks treatment.					
AND					
Clinical criteria:					
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.					
Treatment criteria:					
Must be treated by a paediatric rheumatologist; or					
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.					
Administrative Advice:					
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).					
MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
Administrative Advice: No increase in the maximum number of repeats may be authorised.					
Administrative Advice:					
The assessment for Juvenile Spondyloarthritis Disease Activity Index score is available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4245319/table/T2/ .					
Episodicity: [blank]					
Severity: [blank]					
Condition: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					

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Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition.
AND
Clinical criteria:
Patient must have demonstrated an adequate response to treatment with this drug.
AND
Clinical criteria:
Patient must not receive more than 24 weeks of treatment under this restriction.
Treatment criteria:
Must be treated by a paediatric rheumatologist; or
Must be treated by a rheumatologist; or
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
Prescribing Instructions:
The authority application must be made in writing and must include:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); and
(3) the current Juvenile Spondyloarthritis Disease Activity Index score.
Prescribing Instructions:
An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30%.
Prescribing Instructions:
The assessment of response to treatment must be provided at the time of application and documented in the patient's medical records.
Prescribing Instructions:
An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Prescribing Instructions:
Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
Prescribing Instructions:
If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
Prescribing Instructions:
A patient may re-trial this drug after a minimum of 2 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved and the date of the first application submitted for approval.
Prescribing Instructions:
Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

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<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p> <p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to:</p> <p>Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)</p>
<p>Episodicity: [blank]</p>
<p>Severity: [blank]</p>
<p>Condition: Enthesitis/spondylitis related juvenile idiopathic arthritis</p>
<p>Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis</p>
<p>Treatment Phase: Continuing treatment - balance of supply</p>
<p>Clinical criteria: Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment.</p>
<p>AND</p>
<p>Clinical criteria: The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.</p>
<p>Treatment criteria: Must be treated by a paediatric rheumatologist; or Must be treated by a rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p>
<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)</p>
<p>Episodicity: [blank]</p>
<p>Severity: [blank]</p>
<p>Condition: Enthesitis/spondylitis related juvenile idiopathic arthritis</p>

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Indication: <i>Enthesitis/spondylitis related juvenile idiopathic arthritis</i>
Treatment Phase: <i>Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements</i>
Clinical criteria:
<i>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to [PBS listing date].</i>
AND
Clinical criteria:
<i>Patient must have, prior to initiating treatment with this drug for this condition, a diagnosis of enthesitis/spondylitis related juvenile idiopathic arthritis defined by at least one of the following: (i) peripheral arthritis and enthesitis, (ii) inflammatory sacroiliitis on Magnetic Resonance Imaging (MRI) plus at least 3 months of inflammatory back pain, (iii) arthritis or enthesitis plus at least 2 of: (a) sacroiliac joint tenderness, (b) inflammatory back pain, (c) presence of HLA-B27 antigen, (d) acute (symptomatic) anterior uveitis, (e) history of spondyloarthritis in a first-degree relative</i>
AND
Clinical criteria:
<i>Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for axial disease (sacroiliitis and/or spondylitis), following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs) whilst completing an appropriate exercise program, for a total period of 3 months; or</i>
<i>Patient must have, prior to initiating treatment with this drug for this condition, failed to achieve an adequate response for peripheral disease (arthritis and/or enthesitis) following treatment with at least 2 NSAIDs, and either: (i) methotrexate at a dose of 15 mg per square metre (maximum 20 mg) weekly, (ii) sulfasalazine at a dose of 20 mg/kg (maximum 1 g) twice daily, whilst completing an appropriate exercise program, for a total period of 3 months</i>
AND
Clinical criteria:
<i>Patient must have demonstrated an adequate response to treatment with this drug.</i>
AND
Clinical criteria:
<i>Patient must not receive more than 24 weeks of treatment under this restriction.</i>
Treatment criteria:
<i>Must be treated by a paediatric rheumatologist; or</i>
<i>Must be treated by a rheumatologist; or</i>
<i>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre</i>
Population criteria:
<i>Patient must be under 18 years of age prior to commencement of this drug for this condition</i>
Prescribing Instructions:
<i>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</i>
<i>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</i>
<i>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</i>
<i>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</i>

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Prescribing Instructions:

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Juvenile Spondyloarthritis Disease Activity Index score greater than 2; or
- (b) Persistent symptoms of axial spondylitis or sacroiliitis with prior confirmatory Magnetic Resonance Imaging (MRI) assessed by a clinician experienced with juvenile spondyloarthropathy.

Prescribing Instructions:

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribing Instructions:

The following must be provided at the time of application and documented in the patient's medical records:

- (i) a baseline Juvenile Spondyloarthritis Disease Activity Index score;
- (ii) the current Juvenile Spondyloarthritis Disease Activity Index score;
- (iii) If applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) of the magnetic resonance imaging demonstrating inflammatory spondylitis or sacroiliitis; and
- (iv) If applicable, details (name of the report provider, date of the report and unique identifying number/code that links report to the individual patient) demonstrating the presence of HLA-B27.

Prescribing Instructions:

An adequate response is defined as an improvement from baseline in the Juvenile Spondyloarthritis Disease Activity Index score by at least 30%.

Prescribing Instructions:

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Prescribing Instructions:

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Prescribing Instructions:

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition until 2 years have elapsed. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Administrative Advice:

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Administrative advice:

Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Administrative advice:

This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Administrative Advice:

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Administrative Advice:

Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Summary of matters for PBAC consideration – enthesitis/spondylitis related JIA

- 14.11 Based on feedback from clinical groups and clinicians, and PBAC advice from its March 2024 consideration of this item, proposed new listings for adalimumab for the treatment of paediatric patients with enthesitis or spondylitis related to juvenile idiopathic arthritis (ERA) was provided to the PBAC for consideration. The proposed listings incorporate stakeholder inputs and the TGA-registered indication for adalimumab.
- 14.12 The PBAC was asked to consider whether the proposed eligibility criteria were suitable, including whether the Juvenile Spondyloarthritis Disease Activity Index scoring system with a 30% improvement from baseline score, as proposed in the clinical advice received, is an appropriate measure for adequate response to treatment.
- 14.13 Specialist clinical input indicated that it would be unusual to re-try adalimumab if it was not initially effective. However, a re-treatment period of 2 years was suggested to account for most patients with this subtype of arthritis being diagnosed in adolescence, and therefore would be over the age of 18 after a 5-year treatment gap (as specified in the adult listing for ankylosing spondylitis). A 2-year re-treatment gap would also cater for patients who failed to respond because they did not have a reassessment in the required time frame.
- 14.14 The proposed listing allows for patients who commence treatment with adalimumab when under 18 years of age to continue treatment once a patient turns 18 years. However, if a patient fails to demonstrate a response to adalimumab after turning 18, the patient cannot re-trial treatment with adalimumab. Clinical input suggested that

these patients may qualify for other bDMARDs under the PBS listings for adult indications such as ankylosing spondylitis or non-radiographic axial spondyloarthritis. Additionally, continued use or re-trial of adalimumab is not expected for patients who have failed treatment with the same medication, given that alternative agents are available.

- 14.15 Clinical advice suggested that there may be patients currently accessing adalimumab for this condition through private funding or compassionate supply, and asked whether a grandfather restriction would be appropriate to transition these patients to PBS-subsidised treatment.

For more detail on PBAC’s view, see section 16 PBAC outcome.

15 Financial Estimates

Ankylosing spondylitis

- 15.1 An epidemiological model was used to estimate the financial impact of listing Humira on the PBS for ERA. The sources of data used in the financial estimates are summarised in Table 9 below. Financial estimates are summarised in Table 10.
- 15.2 An estimate of the national prevalence of ERA was calculated using Victorian patient numbers (from clinical input). The model assumes that the proportion of children with ERA nationally is reflective of the number of children with ERA in the Victorian population.

Table 9: Key inputs for financial estimates – Adalimumab – ankylosing spondylitis

Parameter	Value and source
Population	Australian population <18 forecast years (ABS 3222.0 Series B) 2025: 6,225,933 2026: 6,299,095 2027: 6,372,633 2028: 6,442,907 2029: 6,515,378 2030: 6,587,212
Prevalence	0.000007 (A national prevalence was calculated using clinical stakeholder input for Victorian patient numbers)
Proportion of patients with weight 10 kg to <30 kg	10% (values provided by DUSC Secretariat). Assumption: clinical stakeholder input was that most patients are adolescent patients
Proportion of patients with weight ≥30 kg	90% (values provide by DUSC Secretariat). Assumption: clinical stakeholder input was that most patients are adolescent patients
Uptake rate	100% from year 1 of listing
Treatment duration	12 months, based on prevalent patient cohort
Discontinuation	No discontinuation
Switching of treatments	No switching of treatments
Cost	Adalimumab 20 mg: AEMP \$567.42, DPMQ \$649.05 Adalimumab 40 mg: AEMP \$505.95, DPMQ \$558.66

ABS = Australian Bureau of Statistics; AEMP = approved ex-manufacturer price; DPMQ = dispensed price for maximum quantity; DUSC = Drug Utilisation Sub-Committee

Table 10: Financial estimates – adalimumab – ankylosing spondylitis

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated extent of use						
Number of patients treated						
Total initiating patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total continuing patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Number of prescriptions dispensed						
Adalimumab 20 mg/0.2 mL - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab 20 mg/0.2 mL - Continuing	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab 40 mg/0.4 mL - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab 40 mg/0.4 mL - Continuing	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Estimated financial implications						
Net Cost to PBS/RPBS	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges:

¹ < 500

² 500 to < 5,000

³ \$0 to < \$10 million

- 15.3 The cost of treatment is \$█ per patient per year for patients receiving a 20 mg per fortnight dose, and \$█ per patient per year for patients receiving a 40 mg per fortnight dose.
- 15.4 The net cost to the PBS/RPBS was estimated to be \$0 to < \$10 million in year 6, and a net cost of \$0 to < \$10 million in the first 6 years of listing.
- 15.5 Sensitivity analysis was performed using a 10% and 20% increase in the prevalence of ERA. Costings for the sensitivity analysis are summarised in Table 11. The estimated net cost over 6 years was \$0 to < \$10 million and \$0 to < \$10 million for a 10% and 20% increase in prevalence respectively.

Table 11: Sensitivity analysis – adalimumab – ankylosing spondylitis

Sensitivity analysis	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated extent of use – 10% increase in prevalence						
Number of patients treated						
Total initiating patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total continuing patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Net Cost to PBS/RPBS	\$█ ²	\$█ ²	\$█ ²	\$█ ²	\$█ ²	\$█ ²
Estimated extent of use – 20% increase in prevalence						
Number of patients treated						
Total initiating patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total continuing patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Net Cost to PBS/RPBS	\$█ ²	\$█ ²	\$█ ²	\$█ ²	\$█ ²	\$█ ²

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges:

¹ < 500

² \$0 to < \$10 million

Moderate to severe ulcerative colitis

15.6 A market share approach was used to estimate the additional financial impact for allowing dose escalation/dose flexibility of adalimumab for paediatric patients receiving treatment for ulcerative colitis. The sources of data used in the financial estimates are summarised in Table 12 below. Financial estimates are summarised in Table 13.

15.7 Induction dosing of adalimumab for the treatment of ulcerative colitis occurs at week 0 and week 2. The financial estimates model the additional cost to the PBS of allowing flexible dosing from weeks 3 to 16 of treatment. Flexible dosing is permitted under the current adalimumab PBS item codes for continuing therapy of ulcerative colitis (after week 16 of treatment).

Table 12: Key inputs for financial estimates – adalimumab – ulcerative colitis (flexible dosing)

Parameter	Value and source
Population	50% of patients (current market) will require dose escalation. Based on advice from clinical stakeholders.
Prescription volume	Current prescription volumes for initiation item codes (sourced from Medicare statistics).
Dose and treatment duration	Dose escalations of either 20 mg weekly or 40 mg weekly, depending on patient weight, from weeks 3 to 16 of treatment. Dose escalations of 40 mg weekly or 20 mg weekly, depending on patient weight, are already permitted under the current continuing therapy listings for adalimumab for the treatment of ulcerative colitis.
Cost	Adalimumab weekly dose 20mg – Initiating – AEMP \$567.42, DPMQ \$649.05. Adalimumab weekly dose 40mg – Initiating – AEMP \$505.95, DPMQ \$558.66

AEMP = approved ex-manufacturer price; DPMQ = Dispensed price for maximum quantity

Table 13: Financial estimates – Adalimumab – ulcerative colitis (flexible dosing)

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated extent of use						
Number of prescriptions dispensed						
Adalimumab weekly dose 20 mg – Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab weekly dose 40 mg - Initiating	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Total	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Estimated financial implications						
Cost to PBS/RPBS less co-payments	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³
Cost to PBS/RPBS changed listing	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³	-\$█ ³
Net Cost to PBS/RPBS	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³	\$█ ³

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges:

¹ 500 to < 5,000

² < 500

³ \$0 to < \$10 million

15.8 The total net additional cost to the PBS/RPBS for a change to the PBS listing to allow flexible dosing in weeks 3 to 16 of treatment was estimated to be \$0 to < \$10 million in year 6, and a net cost of \$0 to < \$10 million in the first 6 years of listing.

Severe Crohn disease

15.9 A mixed approach (market share and epidemiological approach) was used to model the impact of the proposed changes to the PBS listings for adalimumab for the treatment of paediatric patients with severe Crohn disease. The sources of data used in the financial estimates are summarised in Table 14 below. Financial estimates are summarised in Table 15. Sensitivity analyses were performed altering the percentage of patients with extensive small bowel disease to 3% and 20%. The impact on the financial estimates is show in Table 16.

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Table 14: Key inputs for financial estimates – adalimumab – severe Crohn disease

Parameter	Value and source
Population	Market Share component: 50% of patients will require dose escalation, based on advice from clinical stakeholders. Induction dosing of adalimumab is at week 0 and week 2. The current restrictions for continuation therapy allow weekly dosing. Hence the financial estimates only modelled the item codes for weeks 3-16 at initiating phase. Epidemiological component: Prevalent population for Crohn disease (aged 6-17 years) treated with adalimumab or infliximab. Based on clinician’s advice, 3% of patients have isolated extensive small bowel disease, with up to 20% of patients having a degree of proximal small bowel inflammation associated with their other Crohn disease locations. Hence, 10% was used as the base case, and sensitivity analysis was done using 3% and 20%.
Prescription volume	Market share component: Forecast prescription volumes based on historical utilisation (sourced from Medicare statistics).
Switching	Epidemiological component. Clinical input indicated these patients may be currently treated with infliximab. The model assumed 2% of these patients would switch to adalimumab based on DUSC Secretariat analysis. Assumed the proposed listing would offset infliximab treatment. Both script distribution and dosing regimens of offset medicine relied on dispensing data from the 2023 calendar year.
Patient weight	Epidemiological component: Assumption for population distribution based on the distribution in 2023 (i.e. <40 kg 73% and ≥40 kg 27%).
Dose and treatment duration	Market Share component: 50% of patients will require dose escalation. Based on advice from clinical stakeholders Epidemiological component: Assumed the same dose regimen as per the current listing for Crohn disease, i.e. 16 weeks for initial treatment and 36 weeks for continuing treatment (chronic condition).
Cost	Utilised the AEMP and DPMQ from the existing PBS listings for adalimumab and infliximab (for Crohn disease)

AEMP = approved ex-manufacturer price; DPMQ = Dispensed price for maximum quantity; DUSC = Drug Utilisation Sub-Committee

Table 15: Financial estimates – adalimumab – severe Crohn disease

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated financial implications						
Cost to PBS/RPBS (less co-payments)	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹
Cost to PBS/RPBS changed listing	-\$█ ¹	-\$█ ¹	-\$█ ¹	-\$█ ¹	-\$█ ¹	-\$█ ¹
Net Cost to PBS/RPBS	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

Table 16: Financial estimates – Sensitivity analysis – adalimumab – severe Crohn disease

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated financial implications						
Sensitivity analysis – 3% of patients						
Net Cost to PBS/RPBS	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹
Sensitivity analysis – 20% of patients						
Net Cost to PBS/RPBS	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹	\$█ ¹

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

15.10 Based on the current DPMQ for adalimumab, the estimated net cost to the PBS would be \$0 to < \$10 million in year 6 for the proposed changes to the paediatric Crohn disease listings for adalimumab, with a total cost of \$0 to < \$10 million over 6 years. The net cost to the PBS over 6 years for the sensitivity analyses ranged from \$0 to < \$10 million to \$0 to < \$10 million.

Chronic plaque psoriasis

15.11 Further work was being undertaken to model the financial estimates for the proposal to list adalimumab on the PBS as an earlier line of bDMARD therapy for the treatment of paediatric chronic plaque psoriasis (in patients who do not have an adequate response to topical therapy and phototherapy). This proposal would result in a cost to the PBS.

15.12 Key inputs and financial estimates for an option to list adalimumab for the treatment of chronic plaque psoriasis, in line with the current listings for ustekinumab and etanercept, are shown in Tables 17 and 18 respectively.

Table 17: Source of inputs for Financial estimates – adalimumab for chronic plaque psoriasis (aligned with ustekinumab and etanercept PBS listings)

Parameter	Value and source
Population	Prevalent population based on historical patient numbers for ustekinumab and etanercept provided by DUSC Secretariat.
Patient weight	A 90% and 10% split between ≥40 kg and <40 kg was used to account for the different adalimumab dosing regimens.
Prescriptions	Dispensing data provided by DUSC Secretariat was used to calculate the average script/patient/year for calculating the offset medicines.
Treatment duration	Treatment duration is 12 months since these are prevalent patients.
Switching	2023 PBS data was used to determine the proportion between ustekinumab and etanercept offset. The model assumes 10% of the ustekinumab and etanercept patients are switching to adalimumab.
Cost	Adalimumab 20 mg – AEMP \$567.42, DPMQ \$649.05. Adalimumab 40 mg – AEMP \$505.95, DPMQ \$558.66 Current published AEMPs and DPMQs for ustekinumab and etanercept for CPP listings were used.

AEMP = approved ex-manufacturer price; CPP = chronic plaque psoriasis; DPMQ = Dispensed price for maximum quantity;

DUSC = Drug Utilisation Sub-Committee

Table 18: Financial estimates – adalimumab for chronic plaque psoriasis (aligned with ustekinumab* and etanercept (published prices))

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated extent of use						
Number of patients						
Total initiating patients	1	1	1	1	1	1
Total continuing patients	1	1	1	1	1	1
Estimated financial implications						
Cost to PBS/RPBS – new listing (less co-payments)	\$ 2	\$ 2	\$ 2	\$ 2	\$ 2	\$ 2
Cost to PBS/RPBS changed listing	-\$ 2	-\$ 2	-\$ 2	-\$ 2	-\$ 2	-\$ 2
Net Cost to PBS/RPBS	-\$ 2	-\$ 2	-\$ 2	-\$ 2	-\$ 2	-\$ 2

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme *ustekinumab is subject to a special pricing arrangement with a lower effective price

The redacted values correspond to the following ranges:

¹ < 500

² \$0 to < \$10 million

15.13 At year 6, the estimated net save to the PBS would be \$0 to < \$10 million, and a net save of \$0 to < \$10 million over the first 6 years of listing. The PBAC noted these costs were based on the published price of the alternatives. The net cost to the PBS will increase once the effective price of ustekinumab is applied (see paragraph 13.15).

Severe active juvenile idiopathic arthritis

15.14 The following approach was used to estimate the financial impact of the proposed revised listings of Humira for severe active JIA:

- The total number of JIA patients in Australia based on prevalence was calculated.
- The number of treated PBS patients from the eligible prevalent pool (approximately 1,400) was subtracted.
- It was assumed half of remaining prevalent JIA patients will be eligible to be treated with a JIA listing, i.e. patients with oligoarthritis who are not currently accessing PBS treatment. This was based on UK a study by Shoop-Worrall et al. 2021 reporting 51% of participants had oligoarthritis.⁴⁰
- Market share was applied based on use of current listings to calculate the number of patients who would be treated with adalimumab and a declining growth to the forecast was applied (adalimumab use is decreasing based on PBS use).

⁴⁰ Shoop-Worrall S.J., Hyrich K., Wedderburn L.R., et al, (2021), 'Patient-reported wellbeing and clinical disease measures over time captured by multivariate trajectories of disease activity in individuals with juvenile idiopathic arthritis in the UK: a multicentre prospective longitudinal study', *Lancet Rheumatol*, 3(2):e111-21.

- A treatment uptake rate was applied, assuming it will take time for the health system to adopt the listing changes.

Table 19: Key inputs for financial estimates – Adalimumab – proposed revised listings for severe active JIA

Data	Value and source														
Eligible population															
Juvenile idiopathic arthritis															
Base case	<table border="1"> <thead> <tr> <th>Year</th> <th>Australian population <18 years forecast</th> </tr> </thead> <tbody> <tr> <td>2025</td> <td>2,858</td> </tr> <tr> <td>2026</td> <td>2,892</td> </tr> <tr> <td>2027</td> <td>2,925</td> </tr> <tr> <td>2028</td> <td>2,958</td> </tr> <tr> <td>2029</td> <td>2,990</td> </tr> <tr> <td>2030</td> <td>3,023</td> </tr> </tbody> </table>	Year	Australian population <18 years forecast	2025	2,858	2026	2,892	2027	2,925	2028	2,958	2029	2,990	2030	3,023
	Year	Australian population <18 years forecast													
	2025	2,858													
	2026	2,892													
	2027	2,925													
	2028	2,958													
	2029	2,990													
	2030	3,023													
Source: ABS population - 3222.0 Series B															
Prevalence estimates	43.5 per 100,000 (provided by DUSC Secretariat)														
Treated population	50%														
Eligible patients	50% (provided by DUSC Secretariat)														
Royal Children’s Hospital															
Prevalence estimates	1 in 1,000 (provided by DUSC Secretariat)														
Treated population	22%														
Royal Children’s Hospital															
Prevalence estimates	at least 5,000 children														
Treated population	29%														
Treatment utilisation															
Uptake for patients	100%														
Duration of treatment	chronic treatment														
Discontinuation	no discontinuation														
Switching	no treatment switch														
Costs															
Proposed	20mg AEMP: \$567.42, DPMQ: \$567.42 (s100 public), \$598.79 (s100 private) 40mg AEMP: \$505.95, DPMQ: \$505.95 (s100 public), \$534.86 (s100 private)														

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MBS costs	no change in MBS utilisation
SA Impact	Assumed all restriction at Authority Required (Telephone for initial; streamlined for continue)

ABS = Australian Bureau of Statistics; AEMP = approved ex-manufacturer price; DPMQ = dispensed price for maximum quantity; DUSC = Drug Utilisation Sub-Committee; MBS = Medicare Benefits Schedule; SA = Services Australia

Table 20: Financial estimates – adalimumab – base case severe active JIA

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated extent of use						
Number of patients treated						
Total initiating patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total continuing patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Number of prescriptions dispensed						
Adalimumab (public) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Initiating	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Adalimumab (Private) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Initiating	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Adalimumab (public) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab (Private) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab (public) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Continuing	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (Private) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Continuing	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (public) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Continuing	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (Private) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Continuing	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Total	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Estimated financial implications						
Net Cost to PBS/RPBS	\$ █ ⁵	\$ █ ⁵	\$ █ ⁵	\$ █ ⁵	\$ █ ⁵	\$ █ ⁵

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme
The redacted values correspond to the following ranges:

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- ¹ 500 to < 5,000
- ² < 500
- ³ 5,000 to < 10,000
- ⁴ 20,000 to < 30,000
- ⁵ \$10 million to < \$20 million

Table 21: Financial estimates – adalimumab – severe active JIA (prevalence of 1 in 1,000 patients, 22% treated population)

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated extent of use						
Number of patients treated						
Total initiating patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total continuing patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Number of prescriptions dispensed						
Adalimumab (public) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Initiating	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Adalimumab (Private) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Initiating	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Adalimumab (public) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab (Private) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab (public) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Continuing	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (Private) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Continuing	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (public) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Continuing	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (Private) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Continuing	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Total	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Estimated financial implications						
Net Cost to PBS/RPBS	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵

PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

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The redacted values correspond to the following ranges:

- ¹ 500 to < 5,000
- ² < 500
- ³ 5,000 to < 10,000
- ⁴ 20,000 to < 30,000
- ⁵ \$10 million to < \$20 million

Table 22: Financial estimates – adalimumab – severe active JIA (prevalence of 5,000 patients, 29% treated population)

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
Estimated extent of use						
Number of patients treated						
Total initiating patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Total continuing patients	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Number of prescriptions dispensed						
Adalimumab (public) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Initiating	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Adalimumab (Private) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Initiating	█ ²	█ ²	█ ²	█ ²	█ ²	█ ²
Adalimumab (public) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab (Private) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Initiating	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Adalimumab (public) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Continuing	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (Private) 20 mg/0.2 mL injection, 2 x 0.2 mL syringes - Continuing	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹	PBS: █ ¹
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (public) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Continuing	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Adalimumab (Private) 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices & syringes - Continuing	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³	PBS: █ ³
	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²	RPBS: █ ²
Total	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ⁴
Estimated financial implications						
Net Cost to PBS/RPBS	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵

16 PBAC Outcome

- 16.1 The PBAC recommended the listing of adalimumab for enthesitis/spondylitis related JIA and chronic plaque psoriasis for paediatric patients, and recommended changes to the current listings for adalimumab for moderate to severe ulcerative colitis, severe Crohn disease and JIA for paediatric patients to reflect current evidence and practice in managing these conditions.
- 16.2 The PBAC recalled it had previously considered a submission at its March 2024 meeting, requesting to list Humira as a General Schedule Authority Required (STREAMLINED) listing for the treatment of IMID in paediatric patients. At this meeting it had deferred making a recommendation to allow further consultation with relevant clinical groups. The PBAC had requested advice be sought from clinical groups on the current PBS listings for adalimumab for paediatric conditions, and provide advice on where the listings did not meet current evidence and practice.
- 16.3 The PBAC acknowledged the comprehensive advice received from clinical groups and clinicians from rheumatology, gastroenterology, and dermatology specialties. Advice was provided on how adalimumab is used in practice when managing paediatric patients, and where this differs from the current eligibility criteria for PBS listings for adalimumab for paediatric conditions. The PBAC noted the following advice for adalimumab on the PBS for paediatric patients:
- Suggested new listings for chronic plaque psoriasis and enthesitis/spondylitis related JIA;
 - Suggested changes to the current listings for adalimumab for moderate to severe ulcerative colitis, severe Crohn disease and severe active JIA.

The PBAC noted advice received from the ACD stating that the current listings for adalimumab for hidradenitis suppurativa were appropriate, and no changes were suggested for these listings.

- 16.4 Based on the clinical advice received, the PBAC recommended the following revised and new listings for adalimumab for paediatric patients:
- Changes to the current PBS listings for moderate to severe ulcerative colitis and severe Crohn disease to allow for dose escalation and more flexible dosing. The PBAC noted dose escalations were already permitted for continuing therapy listings for severe Crohn disease and moderate to severe ulcerative colitis, albeit at higher authority level. The PBAC recommended the treatment durations for the different stages of treatment remain the same for these listings.
 - Changes to the clinical criteria of the current Initial therapy PBS listings for severe Crohn disease to facilitate access to paediatric patients with Crohn disease who

have extensive small bowel disease. The PBAC recommended these changes also be flowed on to the PBS listings for infliximab for Crohn disease.

- Changes to the clinical criteria of the current PBS listings for severe active JIA to include a reduced methotrexate dose (15 mg per square metre) as prior treatment, and changes to the Prescribing Instructions for the criteria indicating failure to achieve an adequate response to prior treatment. The PBAC noted clinical advice stating the challenges with measuring response to treatment, and advised that a global assessment of 50% improvement to measure response was appropriate. The PBAC requested that these changes be flowed on to the current PBS listings for etanercept, tocilizumab and tofacitinib for severe active JIA.
 - New listings for chronic plaque psoriasis, consistent with the current PBS listings for other bDMARDs for chronic plaque psoriasis for paediatric patients (etanercept, ustekinumab) and revise the restriction criteria so that patients are allowed to have failed the same bDMARD from twice to once during each treatment cycle.
 - New listings for enthesitis/spondylitis related JIA, aligning with the TGA-registered indication for adalimumab and feedback and advice received from clinical groups and stakeholders. The PBAC advised the proposed eligibility criteria and scoring system to measure adequate response to treatment was appropriate. The PBAC recommended a Grandfather listing for adalimumab for this indication, to allow patients who are currently using adalimumab through self-funding or compassionate access programs and who would otherwise meet the criteria in the recommended listing, to access treatment through the PBS.
- 16.5 The PBAC noted advice provided by the ACD that pustular psoriasis requires urgent medical treatment with a biologic, such as adalimumab. However, the PBAC noted that pustular psoriasis is not a TGA-registered indication for adalimumab, and advised that this condition should not be included in the PBS listings for adalimumab.
- 16.6 The PBAC noted feedback from clinical groups stating that the Authority requirements for adalimumab placed an unnecessary administrative burden for prescribers, reducing time available to provide patient care. The PBAC recommended the Authority requirements for Initial treatment listings for adalimumab for paediatric conditions remain unchanged, but that the Authority requirements for subsequent continuing treatment for these listings be changed to Authority Required (STREAMLINED). For the purposes of dosing escalation for severe Crohn and moderate to severe Ulcerative Colitis, the PBAC advised to not amend the listed quantities, however recommended that the 'no increase to quantity' clauses can be removed from the Streamlined listings to enable higher dosing. The PBAC noted these changes would apply to listings for the treatment of paediatric patients only, with the exception of listings for moderate to severe ulcerative colitis, which include both

paediatric and adult patients in the same listing.

- 16.7 The PBAC acknowledged the collaborative effort and spirit in which the proposed revised and new listings were developed, and the clinical advice provided by clinical groups and clinicians to guide the proposed listings. The PBAC requested the Department provide the clinical groups who gave advice with the relevant recommended listings for adalimumab to ensure the listings are suitable in practice, prior to implementation.
- 16.8 The PBAC noted there are multiple biosimilars for adalimumab listed on the PBS for paediatric conditions. The PBAC recommended that, for current PBS listings for adalimumab where changes were recommended, biosimilars currently listed for these indications be included in these revised listings.
- 16.9 The PBAC recommended that, for the recommended new listings for adalimumab for chronic plaque psoriasis and enthesitis/spondylitis related JIA for paediatric patients, biosimilars that are TGA-registered for these indications be included in these listings
- 16.10 The PBAC noted that the financial and utilisation estimates provided for adalimumab for the new enthesitis/spondylitis related JIA listing were based on a national prevalence calculated using clinical stakeholder input for Victorian patient numbers. It noted sensitivity analysis performed using higher prevalence estimates. PBAC considered the financial and utilisation estimates provided for the new enthesitis/spondylitis related JIA listing to be reasonable.
- 16.11 The PBAC noted clinical advice stating that approximately 50% of patients with moderate to severe ulcerative colitis will require dose escalation with adalimumab. It noted that the listing for adalimumab for this indication includes both paediatric and adult patients. The PBAC considered the financial and utilisation estimates for adalimumab for this indication to be reasonable.
- 16.12 The PBAC noted clinical advice received stating that up to 50% of patients with Crohn disease will require dose escalation with adalimumab. The PBAC also noted advice stating that 3-20% of patients have some small bowel inflammation associated with Crohn disease, and that patients with extensive small bowel disease may be currently using infliximab through the PBS. The PBAC considered the financial and utilisation estimates for adalimumab for this condition to be reasonable.
- 16.13 The PBAC noted financial and utilisation estimates provided for adalimumab for the new chronic plaque psoriasis listings, and that the estimated patient population was based on the number of patients who have used ustekinumab and etanercept for this indication. The PBAC noted that, using the published price for ustekinumab and assuming 10% of patients using ustekinumab or etanercept will switch to adalimumab, there is an estimated net save to the PBS/RPBS.

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- tofacitinib 5 mg tablet, 56 – 13755Y, 13757C, 13737B; tofacitinib 1 mg/mL oral liquid, 240 mL – 13770R, 13738C, 13776C.
- Changes to the clinical criteria for other PBS-listed items for chronic plaque psoriasis, updating the number of times a patient can fail the same bMDARD from twice to once:
 - ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial - 12669T
 - etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack - 1954W; etanercept 50 mg/mL injection, 4 x 1 mL pen devices - 1964J; etanercept 50 mg/mL injection, 4 x 1 mL syringes – 1963H.

The financial implications of the recommended flow-on changes will be worked out as part of the post-PBAC process.

16.19 The PBAC found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met. Specifically the PBAC found that in the circumstances of its recommendation for adalimumab for paediatric conditions:

- a) The treatment is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over alternative therapies, due to adalimumab already being available on the PBS for paediatric patients with moderate to severe ulcerative colitis, Crohn disease and severe active JIA, and other therapies being available on the PBS for paediatric patients for chronic plaque psoriasis;
- b) The treatment is not expected to address a high and urgent unmet clinical need due to adalimumab and other therapies being available on the PBS for paediatric patients with these conditions;
- c) It was not necessary to make a finding in relation to whether it would be in the public interest for the subsequent pricing application to be progressed under Pricing Pathway A because one or more of the preceding tests had failed.

16.20 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

17 Recommended listing

17.1 As there were no changes recommended to the clinical criteria, administrative advice or prescribing instructions (other than standard changes to prescribing instructions and administrative advice necessary for Authority Required STREAMLINED listings)

from what was proposed (Section 14) for listings for moderate to severe ulcerative colitis, severe Crohn disease, severe active JIA and enthesitis/spondylitis related JIA, an abridged version of the recommended listing is presented below. The abridged version of the recommended listings includes the recommended change to Authority Required (STREAMLINED) for the restriction type for subsequent continuing treatment listings, and recommended flow on changes to other PBS listed medicines. Standard administrative advice and prescribing instructions for Authority Required STREAMLINED changes have not been reproduced.

New or amended existing listing as follows:

Chronic plaque psoriasis (new listing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	4	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	4	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	4	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS					
<p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept and ustekinumab for patients under 18 years of age with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept and ustekinumab only.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.</p> <p>A patient who is receiving PBS-subsidised treatment for severe chronic plaque psoriasis is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive</p>					

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multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was prescribed in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 times in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

There are separate restrictions for the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hand and foot.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

(i) a patient has never received PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - Biological medicine-naive patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine or recommence with the same biological medicine within the same treatment cycle (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept within 12 months (Initial 4) due to a disease flare with psoriasis affecting the whole body if:

(i) there is at least a 50% change in the patients PASI score compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(ii) the patient has a current PASI score greater than 15

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Etanercept only:

After completing 24-weeks of treatment with PBS-subsidised etanercept, a patient is eligible for re-treatment with etanercept (Initial 4) due to a disease flare with psoriasis affecting the face, hand or foot if:

(i) all subscores are rated moderate to severe; or

(ii) 2 of the three subscores are rated severe to very severe; or

(iii) the affected area of skin has increased by at least 50% compared to that at the time of the last assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept; or

(iv) the area affected is 30% or more of the face, palm of a hand or sole of a foot,

(2) Assessment of response to initial treatment.

After prescribing initial treatment with a biological medicine, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment will be used to determine eligibility for continuing treatment and must be conducted within 8 weeks of the last administered dose.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Adalimumab and Ustekinumab only:

To avoid an interruption of supply for **First** continuing treatment, the assessment should be submitted no later than 2 weeks prior to when the next dose (under the new authority application) is due, unless the patient is currently on a treatment break.

(3) Continuing treatment

Etanercept only:

Following the completion of an initial 16-week treatment course with etanercept, a patient may receive a further 8 weeks of treatment (under the 'Completion of course' treatment phase) to complete a 24-week treatment course, providing they have demonstrated an adequate response to treatment to the initial supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be documented in the patient's medical records. Where a response assessment is not conducted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and Ustekinumab only:

Following the completion of an initial ~~28-week~~ treatment course with a **specific biological medicine**, a patient may qualify to receive up to 24 weeks per continuing treatment course **under the First continuing with that drug** provided they demonstrate an adequate response to treatment. The patient remains eligible to receive continuing treatment in courses of up to 24 weeks **under the Subsequent continuing treatment restriction with that drug** provided they continue to sustain the response. It is recommended that a patient be reviewed 4 weeks prior to when their next dose (under a new authority application) is due to ensure uninterrupted supply, but no later than 8 weeks after the date of the last administered dose.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

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deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to the prior non-biological therapy requirements. If the patient has had a break in therapy of more than 5 years, the indices of disease severity need to be met, but a re-trial of non-biological therapy is not required.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to that biological medicine **more than once** within the same treatment cycle or have failed to respond to biological medicines, as an aggregate, on 3 occasions within the same treatment cycle.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment must be demonstrated based on the baseline PASI assessment provided with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is provided within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment. Where a patient is changing from treatment with etanercept to **adalimumab or ustekinumab** the prescriber must provide a baseline PASI measurement, as well as a PASI score demonstrating a response to treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6A) Recommencement of treatment after a break of less than 5 years in PBS-subsidised therapy (all drugs except etanercept).

A patient who wishes to resume treatment following a break in PBS-subsidised therapy of less than 5 years must resume under the 'Initial 2' treatment phase. The most recent PASI assessment demonstrating disease flare must be no more than 4 weeks old at the time of application.

(6B) Re-treatment (etanercept only)

A patient may be re-treated, in certain circumstances, with etanercept after completing a 24-week treatment course under the 'Initial 4' treatment phase.

(7) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to undertake a new treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under an 'Initial 3' treatment phase.

Administrative Advice: No increase in the maximum number of repeats may be authorised.

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Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
Indication: Severe chronic plaque psoriasis
Treatment Phase: Initial treatment (Whole body) - biological medicine-naive patient
Treatment criteria:
Must be treated by a dermatologist
Clinical criteria:
Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis
AND
Clinical criteria:
Patient must not have received PBS-subsidised treatment with a biological medicine for this condition
AND
Clinical criteria:
The treatment must be as systemic monotherapy; OR
The treatment must be in combination with methotrexate,
AND
Clinical criteria:
Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,
AND
Clinical criteria:
Patient must not receive more than 17 weeks of treatment under this restriction
Population criteria:
Patient must be under 18 years of age
Prescribing Instructions: Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

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<p>Prescribing Instructions Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application</p>
<p>Prescribing Instructions Details of the accepted toxicities including severity can be found on the Services Australia website.</p>
<p>Prescribing Instructions The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>
<p>Prescribing Instructions:</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:</p> <p>(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.</p> <p>A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of:</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined.</p> <p>Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)</p>
<p>Indication: Severe chronic plaque psoriasis</p>
<p>Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years</p>
<p>Treatment criteria:</p>
<p>Must be treated by a dermatologist</p>
<p>AND</p>
<p>Clinical criteria:</p>
<p>The treatment must be as systemic monotherapy; OR</p>
<p>The treatment must be in combination with methotrexate,</p>
<p>AND</p>

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Clinical criteria:
<i>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle.</i>
AND
Clinical criteria:
<i>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle</i>
AND
Clinical criteria:
<i>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle</i>
AND
Clinical criteria:
<i>Patient must not receive more than 17 weeks of treatment under this restriction</i>
Population criteria:
<i>Patient must be under 18 years of age</i>
Prescribing Instructions:
<i>The authority application must be made in writing and must include:</i> <i>(1) a completed authority prescription form; and</i> <i>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</i>
Prescribing Instructions:
<i>Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.</i>
Prescribing Instructions:
<i>Response to preceding supply:</i> <i>An adequate response to treatment is defined as:</i> <i>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</i>
<i>Change in therapy:</i> <i>If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because:</i> <i>(i) there is an absence of an adequate response to that treatment; or</i> <i>(ii) there was an intolerance to that treatment; or</i> <i>(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above</i>
<i>Recommencing therapy:</i> <i>If the patient is recommencing therapy, in relation to the last administered dose, state whether there was:</i> <i>(i) an absence of an adequate response; or</i> <i>(ii) an intolerance to that treatment; or</i> <i>(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.</i>
Prescribing Instructions:
<i>The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</i>

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Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
Indication: Severe chronic plaque psoriasis
Treatment Phase: Initial 3 (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years
Treatment criteria:
Must be treated by a dermatologist
AND
Clinical criteria:
Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle
AND
Clinical criteria:
The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words "whole body"; or
The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words "face, hand, foot"
AND
Clinical criteria:
Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or
The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot
AND
Clinical criteria:
The treatment must be as systemic monotherapy; or
The treatment must be in combination with methotrexate
AND
Population criteria:
Patient must be under 18 years of age
Patient must not receive more than 17 weeks of treatment under this restriction
Prescribing Instructions:
The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.
Prescribing Instructions:
The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					

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adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	0	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online)					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)					
[overarching admin note not reproduced]					
No increase in the maximum number of repeats may be authorised.					
Treatment criteria:					
Must be treated by a dermatologist					
AND					
Treatment Criteria					
Patient must be undergoing currently PBS-subsidised treatment with this biological medicine					
AND					
Clinical criteria:					
The treatment must be as systemic monotherapy; or					
The treatment must be in combination with methotrexate					
AND					
Clinical criteria:					
Patient must not receive more than 17 weeks of treatment under this restriction, but has received insufficient therapy to complete 17 weeks treatment under any of the initial treatment phases (regardless of affected body area): (i) initial 1, (ii) initial 2, (iii) initial 3.					
AND					
Clinical criteria:					
The treatment must provide no more than the balance of 17 weeks treatment available under any of the initial treatment phases					
Administrative Advice:					
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday)					

Indication: Severe chronic plaque psoriasis
Treatment Phase: Initial 1 treatment (face, hand, foot) - biological medicine-naive patient
Treatment criteria:
Must be treated by a dermatologist
Clinical criteria:

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<i>Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis</i>
AND
Clinical criteria:
<i>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition</i>
AND
Clinical criteria:
<i>The treatment must be as systemic monotherapy; OR</i>
<i>The treatment must be in combination with methotrexate,</i>
AND
Clinical criteria:
<i>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,</i>
AND
Clinical criteria:
<i>Patient must not receive more than 17 weeks of treatment under this restriction</i>
Population criteria:
<i>Patient must be under 18 years of age</i>
Prescribing Instructions:
<i>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.</i>
Prescribing Instructions
<i>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application</i>
Prescribing Instructions
<i>Details of the accepted toxicities including severity can be found on the Services Australia website.</i>
Prescribing Instructions
<i>The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</i>

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Prescribing Instructions:

The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy:

(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or

(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy

Provide in this authority application, and document in the patient's medical records, each of:

(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;

(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);

(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;

(iv) the dates that response assessments were determined.

Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment:

(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);

(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.

Category / Program: GENERAL - General Schedule (Code GE)

Prescriber type: Medical Practitioners

Restriction type: Authority Required (in writing only via post/HPOS upload)

Indication: Severe chronic plaque psoriasis

Treatment Phase: Initial 2 treatment (face, hand, foot) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years

Treatment criteria:

Must be treated by a dermatologist

AND

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

Clinical criteria:

Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle.

AND

Clinical criteria:

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle

AND

Clinical criteria:

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle

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AND
Clinical criteria:
Patient must not receive more than 17 weeks of treatment under this restriction
Population criteria:
Patient must be under 18 years of age
Prescribing Instructions: The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
Prescribing Instructions: Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.
Prescribing Instructions: Response to preceding supply: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was: (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.
Prescribing Instructions: The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira

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Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
[overarching admin note not reproduced for conciseness]
Administrative Advice: No increase in the maximum number of repeats may be authorised.
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001
Indication: Severe chronic plaque psoriasis
Treatment Phase: First continuing treatment, Whole body
Treatment criteria: Must be treated by a dermatologist
AND
Clinical criteria: Patient must have received this drug as their most recent course of PBS-subsidised treatment for this condition
AND
Clinical criteria: The treatment must be as systemic monotherapy; OR
The treatment must be in combination with methotrexate,
AND
Clinical criteria: Patient must have demonstrated an adequate response to treatment with this drug
AND
Clinical criteria: Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine
AND
Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction
Prescribing Instructions: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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<p>Prescribing Instructions: Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>
<p>Prescribing Instructions: The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.</p>
<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)</p>
<p>Indication: Severe chronic plaque psoriasis</p>
<p>Treatment Phase: First continuing treatment (Face, hand, foot)</p>
<p>Treatment criteria: Must be treated by a dermatologist</p>
<p>Clinical criteria: Patient must have received this drug as their most recent course of PBS-subsidised treatment for this condition</p>
<p>AND</p>
<p>Clinical criteria: The treatment must be as systemic monotherapy; OR</p>
<p>The treatment must be in combination with methotrexate,</p>
<p>AND</p>
<p>Clinical criteria: Patient must have demonstrated an adequate response to treatment with this drug</p>
<p>AND</p>
<p>Clinical criteria: Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine</p>
<p>AND</p>
<p>Clinical criteria: Patient must not receive more than 24 weeks of treatment under this restriction</p>
<p>Prescribing Instructions: An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p>

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Prescribing Instructions:

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Prescribing Instructions:

The authority application must be made in writing and must include:

- (a) details of the proposed prescription(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira
Prescribing rule	Amended 31185	[overarching admin note not reproduced for conciseness]			
	7607	Administrative Advice: No increase in the maximum number of repeats may be authorised.			
	7606	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.			
	28496 CAR	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).			
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED)					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Subsequent continuing treatment (Whole body)					
Treatment criteria:					
Must be treated by a dermatologist					
Clinical criteria:					
Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction					
AND					
Clinical criteria:					
Patient must have demonstrated an adequate response to treatment with this drug					

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AND
Clinical criteria:
Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine
AND
Clinical criteria:
Patient must not receive more than 24 weeks of treatment under this restriction
Prescribing Instructions:
An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.
Prescribing Instructions:
The assessment of response to treatment must be documented in the patient's medical records.
Prescribing Instruction
The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED)
Indication: Severe chronic plaque psoriasis
Treatment Phase: Subsequent continuing treatment (Face, hand, foot)
Treatment criteria:
Must be treated by a dermatologist
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction
AND
Clinical criteria:
Patient must have demonstrated an adequate response to treatment with this drug
AND
Clinical criteria:
Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine
AND
Clinical criteria:
Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction
Prescribing Instructions:
An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value.
Prescribing Instructions:
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Prescribing Instructions:

The assessment of response to treatment must be documented in the patient's medical records.

17.2 Flow-on changes to etanercept and ustekinumab to amend the failure of the same bDMARD within the same treatment cycle from twice to once.

Moderate to severe ulcerative colitis (change to existing listing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12347W	3	6	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12359L	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12382Q	3	6	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12374G	3	3	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe	12339K	3	3	0	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12371D	1	2	3	Humira

Category / Program: GENERAL - General Schedule (Code GE)

Prescriber type: Medical Practitioners

Restriction type: Authority Required (in writing only via post/HPOS upload)

Indication: Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Category / Program: GENERAL - General Schedule (Code GE)

Prescriber type: Medical Practitioners

Restriction type: Authority Required (in writing only via post/HPOS upload)

Indication: Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Category / Program: GENERAL - General Schedule (Code GE)

Prescriber type: Medical Practitioners

Restriction type: Authority Required (in writing only via post/HPOS upload)

Indication: Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					

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adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12347W	3	6	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12412G	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12359L	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12382Q	3	6	0	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12371D	1	2	3	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12337H	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12358K	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12391E	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: First continuing treatment					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: Continuing treatment - balance of supply					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system) (STREAMLINED)					

Indication: Moderate to severe ulcerative colitis
Treatment Phase: Subsequent continuing treatment

17.3 Flow-on changes to remove the no increases in quantity to allow dosing escalation for all adalimumab biosimilars currently listed on the PBS .

Severe Crohn disease (change to existing listing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12407B	1	2	3	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12373F	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12338J	1	2	2	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12432H	3	6	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12455M	3	6	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device	12426B	3	3	0	Humira
adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe	12409D	3	3	0	Humira

Category / Program: GENERAL - General Schedule (Code GE)

Prescriber type: Medical Practitioners

Restriction type: Authority Required (in writing only via post/HPOS upload)

Indication: Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Category / Program: GENERAL - General Schedule (Code GE)

Prescriber type: Medical Practitioners

Restriction type: Authority Required (in writing only via post/HPOS upload)

Indication: Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Category / Program: GENERAL - General Schedule (Code GE)

Prescriber type: Medical Practitioners

Restriction type: Authority Required (in writing only via post/HPOS upload)

Indication: Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12423W	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12411F	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12379M	1	2	0	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Indication: Severe Crohn disease					
Treatment Phase: Balance of supply for paediatric patient					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12424X	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12341M	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12413H	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> General Schedule					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (HPOS/online)					
Indication: Severe Crohn disease					
Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI					
Indication: Severe Crohn disease					
Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira

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Category / Program: <input checked="" type="checkbox"/> General Schedule
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED)
Indication: Severe Crohn disease
Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient

17.4 Flow-on changes to remove the no increases in quantity to allow dosing escalation for all adalimumab biosimilars currently listed on the PBS.

17.5 Flow-on changes to infliximab 100 mg injection, 1 vial:

- 5755X and 9612X (Initial treatment – Initial 1 (new patient)): add new restrictions
- 5755X and 9612X (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)): add new restriction
- 5755X and 9612X (First continuing treatment): remove restrictions, replace restriction and add new restriction
- 11445J, 11448M, 11449N and 11450P (subsequent continuing treatment): remove restrictions, replace restriction and add new restriction.

Severe active juvenile idiopathic arthritis (change to existing listing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12406Y	1	2	0	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	12443X	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12335F	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	12444Y	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12431G	1	2	0	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	12396K	1	2	0	Humira
Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)					
Indication: Severe active juvenile idiopathic arthritis					
Treatment Phase: Initial treatment - Initial 1 (new patient)					
Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					

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Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)
Indication: Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)
Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)
Indication: Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)
Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)
Indication: Severe active juvenile idiopathic arthritis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	13292N	1	2	5	Humira
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	13293P	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13210G	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13229G	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	13212J	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	13228F	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)					

Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)
Indication: Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

- 17.6 Flow-on changes to Adalcip, Hadlima and Yuflyma that are currently listed under the PBS item codes above.
- 17.7 Flow-on changes to etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1:
- 5734T, 6367D (Initial treatment – Initial 1 (new patient)): change restrictions
 - 5734T, 6367D (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months): change restriction
 - 5734T, 6367D (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months): change restrictions
 - 13294Q, 13295R (Continuing treatment): change restriction
- 17.8 Flow-on changes to etanercept 50 mg/mL injection, 4 x 1 mL pen devices:
- 5735W, 9641K (Initial treatment – Initial 1 (new patient)): change restrictions
 - 5735W, 9641K (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months): change restriction
 - 5735W, 9641K (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months): change restrictions
 - 13119B, 13326J (Continuing treatment): change restriction
- 17.9 Flow-on changes to etanercept 50 mg/mL injection, 4 x 1 mL syringes:
- 5733R, 9615C (Initial treatment – Initial 1 (new patient)): change restrictions
 - 5733R, 9615C (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months): change restriction
 - 5733R, 9615C (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months): change restrictions
 - 13308K, 13332Q (Continuing treatment): change restriction
- 17.10 Flow-on changes to 80 mg/4 mL injection, 4 mL vial:

- 1419Q, 1476Q, 10068X, 10077J (Initial treatment – Initial 1 (new patient)): change restriction
- 1419Q, 1476Q, 10068X, 10077J (Initial treatment – Initial 2 (retrial or recommencement of treatment after a break of less than 12 months): change restriction
- 1419Q, 1476Q, 10068X, 10077J (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months): change restriction
- 12794J, 12811G (Initial treatment – Initial 4 (Temporary listing – change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab): change restrictions
- 13304F, 13315T (Continuing treatment): change restriction
- 13324G (Continuing treatment): change restriction

17.11 Flow-on changes to tocilizumab 200 mg/10 mL injection:

- 1423X, 1481Y (Initial treatment – Initial 1 (new patient)): change restriction
- 1423X, 1481Y (Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)): change restriction)
- 1423X, 1481Y (Initial treatment – Initial 3 (recommencement of treatment after a break of more than 12 months)): change restriction
- 10056G, 10079L (Initial treatment – Initial 1 (new patient)): change restrictions
- 10056G, 10079L (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)): change restriction
- 10056G, 10079L (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)): change restrictions
- 12795K, 12796L (Initial treatment – Initial 4 (Temporary listing – change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab): change restrictions
- 13305G, 13312P (Continuing treatment): change restriction
- 13329M, 13330N (Continuing treatment): change restriction

17.12 Flow-on changes to tocilizumab 400 mg/20 mL injection, 20 mL vial:

- 10060L, 10064Q (Initial treatment – Initial 1 (new patient)): change restrictions

- 10060L, 10064Q (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)): change restriction
- 10060L, 10064Q (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)): change restrictions
- 12802T, 12810F (Initial treatment – Initial 4 (Temporary listing – change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)): change restrictions
- 1464C, 1482B (Initial treatment – Initial 1 (new patient)): change restriction
- 1464C, 1428B (Initial treatment – Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)): change restriction
- 1464C, 1428B (Initial treatment – Initial 3 (recommencement of treatment after a break of more than 12 months)): change restriction
- 13299Y, 13323F (Continuing treatment): change restriction
- 13338B, 13339C (Continuing treatment): change restriction

17.13 Flow-on changes to tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices:

- 12085C, 12083Y (Initial treatment – Initial 1 (new patient weighing less than 30 kg)): change restriction
- 12085C, 12083Y (Initial treatment – Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg): change restriction
- 12085C, 12083Y (Initial treatment – Initial 3) (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg): change restriction
- 12767Y (Initial treatment – Initial 4 (Temporary listing – change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)): change restriction
- 11725D (Initial treatment – Initial 1 (new patient)): change restrictions
- 11725D (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)): change restriction
- 11725D (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)): change restriction
- 11734N (Initial treatment – Initial 1 (new patient)): change restrictions

- 11734N (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)): change restriction
- 11734N (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)): change restrictions
- 11742B, 13306H (Continuing treatment): change restriction
- 12084B, 12090H (Continuing treatment in a patient weighing at least 30 kg): change restriction

17.14 Flow-on changes to cilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes:

- 12105D, 12095N (Initial treatment – Initial 1 (new patient weighing less than 30 kg): change restriction
- 12105D, 12095N (Initial treatment – Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg)): change restriction
- 12105D, 12095N (Initial treatment – Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)): change restriction
- 12768B (Initial treatment – Initial 4 (Temporary listing – change of treatment from another biological medicine to cilizumab after resolution of the critical shortage of cilizumab)): change restriction
- 11748H (Initial treatment – Initial 1 (new patient)): change restrictions
- 11748H (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)): change restriction
- 11748H (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)): change restrictions
- 11720W, 13301C (Continuing treatment): change restriction
- 12086D, 12099T (Continuing treatment in a patient weighing less than 30 kg): change restriction

17.15 Flow-on changes to tofacitinib 5 mg tablet, 56:

- 13755Y (Initial treatment – Initial 1 (new patient)): change restrictions
- 13755Y (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)): change restriction
- 13755Y (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)): change restriction

- 13757C (Transitioning from non-PBS to PBS-subsidised supply – Grandfather arrangements): change restriction
- 13737B (Continuing treatment): change restriction

17.16 Flow-on changes to tofacitinib 1 mg/mL oral liquid, 240 mg:

- 13770R (Initial treatment – Initial 1 (new patient)): change restrictions
- 13770R (Initial treatment – Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)): change restriction
- 13770R (Initial treatment – Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)): change restrictions
- 13738C (Continuing treatment): change restriction
- 13776C (Transitioning from non-PBS to PBS-subsidised supply – Grandfather arrangements): change restrictions

Enthesitis/spondylitis related juvenile idiopathic arthritis (new listing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	3	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	3	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	3	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Initial treatment					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Episodicity: [blank]					
Severity: [blank]					
Condition: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Initial treatment - balance of supply					

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED)					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Continuing treatment					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes	NEW	1	2	5	Humira
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices	NEW	1	2	5	Humira
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Episodicity: [blank]					
Severity: [blank]					
Condition: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Continuing treatment - balance of supply					
Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Episodicity: [blank]					
Severity: [blank]					
Condition: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements					

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

18 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

19 Sponsor's Comment

AbbVie welcomes the PBAC's recommendation to expand access to adalimumab and other advanced treatments for children with psoriasis, juvenile arthritis, and inflammatory bowel disease, while also acknowledging the extensive consultation undertaken by both AbbVie and the Department of Health throughout the course of this submission. We would like to thank the clinicians, organisations, patients and family members who have shared their expertise, experience, and support through the preparation, evaluation, and broader consumer consultation process for this submission. AbbVie remains committed to working closely with all stakeholders to ensure the final restrictions are clinically appropriate and address the existing problems and inequities in access for paediatric patients.