

7.12 INFLIXIMAB, injection vial, 100 mg, Remicade[®], Janssen-Cilag Pty Ltd

1 Purpose of Application

- 1.1 The minor resubmission sought an extension to listing on the basis of a revised best estimate of the ICER following the March 2014 PBAC positive recommendation to extend the listing of infliximab to include the treatment of moderate to severe ulcerative colitis.

2 Requested listing

- 2.1 The requested listing remained unchanged from that requested in the March 2014 major submission. An initial (written Authority), first continuing (written Authority) and a second and subsequent (telephone Authority) restriction were sought in March 2014.
- 2.2 The minor resubmission noted the PBAC recommendation from the March 2014 meeting that all continuation scripts should be via Authority required telephone approvals. However, the re-submission maintained the original request to separate the continuing restriction into a first (written Authority) and second and subsequent continuing (telephone Authority) restriction. The re-submission reiterated that this is in the interest of reducing prescriber administrative burden. In addition, the sponsor advised that this request is consistent with a concurrent minor PBAC submission requesting changes to all of the PBS listings for Janssen's products (infliximab, golimumab and ustekinumab; see agenda item number 6.5). The Secretariat noted that this proposal would place greater administrative burden on clinicians than compared to one telephone continuing Authority restriction. In the context of a risk-share proposal, an initial continuing Authority required restriction that is 'written only' would aid the sponsor in reducing financial risk.
- 2.3 At the March 2014 meeting, the PBAC agreed with the Secretariat's suggestion of one continuing restriction for infliximab. The PBAC agreed that one continuing restriction (as opposed to an initial continuing and a second and subsequent continuing restriction) for consistency with the Crohn's disease listing and on the basis that there did not appear to be any significant difference between the criteria of the proposed 'initial continuing' and 'subsequent continuing' restrictions.
- 2.4 The PBAC noted the minor re-submission's reiteration (see pre-PBAC response, p3) for a Grandfather clause to be included in the restriction. The sponsor estimated that approximately ■■■ patients may be affected, with ■■■ patients currently receiving infliximab through sponsor compassionate supply arrangements and the rest likely to be receiving treatment through publicly funded hospitals.

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

3 Background

- 3.1 Infliximab is TGA registered for the treatment of moderately severe to severe active ulcerative colitis in patients who have had an inadequate response to conventional

therapy, in adults and in children/adolescents (6 to 17 years), in addition to various other indications.

- 3.2 This was the PBAC's second consideration of infliximab for moderate to severe ulcerative colitis.
- 3.3 At the March 2014 meeting, the PBAC recommended extending infliximab's listing to include a Section 100 (Highly Specialised Drugs Program) Authority required benefit listing for the treatment of moderate to severe ulcerative colitis in adults and children.
- 3.4 The PBAC considered Economics Subcommittee (ESC) specified estimate of the incremental cost-effectiveness ratio (ICER) to be the most reliable basis for estimating the true ICER. However, the PBAC considered the ICER range of \$45,000/QALY - \$75,000/QALY as estimated by the submission's revised economic model and the ESC's revised economic model, to be unacceptably high.
- 3.5 The PBAC further considered a lower ICER (in the range of \$15,000/QALY - \$45,000/QALY), as determined by the ESC's revised economic model, would be acceptable to enable infliximab to be considered cost-effective for use in ulcerative colitis.

4 Clinical place for the proposed therapy

- 4.1 This was unchanged from the March 2014 major submission.

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

5 Comparator

- 5.1 No change was proposed to that considered in the March 2014 major submission. Best supportive care was the comparator in March 2014.

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

6 Consideration of the evidence

Sponsor hearing

- 6.1 As a minor submission, there was no hearing for this item.

Consumer comments

- 6.2 The PBAC noted and welcomed the input from individuals (4) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with infliximab including the ability to dramatically reduce disease symptoms, helping to avoid personal embarrassment and increasing patient confidence.

Clinical trials

- 6.3 No new clinical trials were presented in the minor resubmission.

Clinical claim

- 6.4 No new clinical claims were made compared to the March 2014 major submission.
- 6.5 The minor resubmission reiterated that results of an indirect comparison of infliximab to adalimumab show that infliximab is superior at inducing remission in patients with moderate to severe ulcerative colitis.

Economic analysis

- 6.6 The PBAC noted that the clinical data, structure of the economic model and price were the same as that presented in the March 2014 major submission.
- 6.7 The minor resubmission revised a number of model parameters and input values for the following reasons as outlined in the table below:

Model parameter revised for July 2014 and rationale

Differences between this minor resubmission and past major submission	Minor resubmission's rationale
Half cycle correction	Amending an error
Vials of infliximab per dose	Updated to the weight of Australian patients and incorporating use in paediatric patients
Hospital days for cyclosporin treatment	Correction of an error
Health state costs including post-surgery	Best available evidence and addition of ongoing ostomy costs
Disutility of post-surgery remission	Midway between two estimates used in published models and equal to a value used in a third economic model
Loss of response in placebo treated patients with severe disease from week 30 to week 54	Reflecting the ACT trial evidence
Surgery mortality risk	Best available evidence
Utility values from Tsai 2008	Not used in the base case. Presented to allow a comparison to other economic models in ulcerative colitis

- 6.8 When the 8 parameters were revised for what the minor resubmission considered to be the best estimate, the ICER was calculated by the minor re-submission to be in the range of \$45,000/QALY - \$75,000/QALY. This ICER was verified by the evaluation.
- 6.9 For health state utility values, the PBAC noted that the resubmission used the values from Tsai (2008) in a sensitivity analysis (the base case utilities in the resubmission and previous submission were both derived from the ACT trials). The re-submission assumed that all patients in non-remission have moderate to severe disease. As this may not have been reasonable, the evaluation of this minor resubmission provided an additional sensitivity analysis by assuming that 70% of the patients in the non-remission state have moderate to severe disease with the remaining having a response, but not remission.
- 6.10 The PBAC noted the additional sensitivity analyses undertaken during the evaluation based on the use of Australian utility values for patients with ulcerative colitis from a recently published study (Gibson et al. (2013)). This study was a cross-sectional observational study which measured the quality of life in 175 patients with ulcerative colitis in Australia, using the EQ-5D and AQoL quality of life instruments. Using the EQ-5D instrument, the utility value for remission was 0.81 and for moderate to severe disease 0.68. Using the AQoL instrument, the utility value for remission was 0.80 and

for moderate to severe disease 0.66. [REDACTED]

[REDACTED] The PBAC noted that the resubmission’s base case used utility values from the ACT trials and considered this to be reasonable.

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

6.11 The minor submission claimed that the ICER in the range of \$45,000/QALY - \$75,000/QALY is comparable to that estimated for Crohn’s disease and fistulising Crohn disease as previously recommended by the PBAC and was therefore acceptable. The PBAC noted a comparison table (shown below) of past infliximab ICERs and PBAC considerations of these ICERs in inflammatory bowel indications.

Comparison table of past ICERs and PBAC comments

PBAC meeting	Indication	ICER	PBAC Comments
March 2010	Fistulising Crohn disease	\$45,000/QALY - \$75,000/QALY [REDACTED]	The PBAC considered the ICER to be high but acceptable. The results of the sensitivity analyses indicated that the model is most sensitive to changes in utility values. The model was also sensitive to hospitalisation cost offsets. The inclusion of hospitalisation costs lowered the incremental cost-effectiveness ratios substantially. The PBAC also noted that there was uncertainty about the hospital and procedure costs, based on a UK study included in the submission, which may have overestimated costs, favouring infliximab. There was also some uncertainty about the reliability of the Australian study used to derive utility values as a source for utilities with and without fistula closure. However, these uncertainties were not considered sufficient to warrant rejection of the submission.
July 2007	Crohn disease – paediatric	\$15,000/QALY - \$45,000/QALY [REDACTED]	The PBAC questioned the utility values derived from a small survey of Australian clinicians and agreed that the utility values obtained lacked face validity.
March 2007	Crohn disease - adult	\$45,000/QALY - \$75,000/QALY [REDACTED]	The PBAC considered that the ICER is high and uncertain and considered if it would be limited to severe population (CDAI >300), the incremental cost-effectiveness ratio would improve sufficiently (albeit by an unknown amount). The submission proposed a patient population of CDAI >220.

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

Estimated PBS usage & financial implications

6.12 No further changes to the estimated PBS usage and financial implications in the March 2014 major submission were made in the minor resubmission.

- 6.13 The minor resubmission disagreed with a 100% rebate subsidisation cap as it argued that such a cap does not reflect the benefit received by partial responders. The minor resubmission proposed a risk sharing arrangement (RSA) similar to the RSA for the Crohn's indication (i.e. [REDACTED]).
- 6.14 The PBAC reaffirmed its March 2014 recommendation with regards to the requirement for a risk share agreement between the Government and sponsor for the reasons of limiting PBS expenditure arising from a higher than expected number of patients accessing maintenance therapy due to the use of a partial Mayo score as opposed to the full Mayo score, and, the potential for partial responders to continue treatment despite not meeting the continuing treatment eligibility criteria.
- 6.15 The PBAC considered, among other matters, that its assessment of the cost-effectiveness of infliximab in moderate to severe ulcerative colitis would be acceptable if the measures below were implemented to contain risks associated with the cost of infliximab to the PBS:
- A risk share Agreement between the sponsor and the Government;
 - Annual financial PBS expenditure estimates be based on:
 - 1) PBS restrictions requiring the use of a partial Mayo score (as opposed to a full Mayo score); and
 - 2) trial-based estimates of the percentage of patients continuing with maintenance treatment;
 - Government expenditure above any subsidisation cap/s derived from the description above to be rebated at a percentage to be negotiated by the Department.

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

7 PBAC Outcome

- 7.1 The PBAC recommended extending the current Section 100 (Highly Specialised Drugs Program) listing of infliximab to include an Authority required listing for the treatment of patients with moderate to severe ulcerative colitis, on the basis of acceptable cost-effectiveness compared to best supportive care.
- 7.2 For the requested listing, the PBAC recalled that its recommendation from March 2014 was for a complex written-only Authority initial restriction and one continuing restriction that could be a telephone Authority approval. This would differ from infliximab's Crohn's disease listing which is a complex written-only Authority listing for initial treatment and all continuing treatment. The PBAC remained of the view that the continuing restriction for the moderate to severe ulcerative colitis indication could allow telephone Authority approval. The PBAC noted the resubmission's request to separate continuing treatment into a complex written-only Authority required first continuing listing and a telephone Authority required listing for second and subsequent approvals but did not accept this proposal at this point in time, noting the Department's PBS Authority required Review arising from the 2014-15 Health Portfolio Budget Statement was about to commence.
- 7.3 The PBAC noted that the clinical place for infliximab would be as the first PBS-subsidised tumour-necrosis factor alpha inhibitor for moderate to severe ulcerative

colitis for use after an inadequate response to either azathioprine, 6-mecaptopurine or a tapered course of oral steroids.

- 7.4 The comparator of best supportive care had previously been accepted by the PBAC as the appropriate comparator and this had remained unchanged in the minor resubmission.
- 7.5 The PBAC's views on infliximab's comparative benefits and harms remained unchanged from those formed in March 2014.
- 7.6 The minor resubmission's respecified ICER in the range of \$45,000/QALY - \$75,000/QALY gained was considered to be reasonably reliable by the PBAC. The PBAC agreed that the previous respecified ICER in the range of \$45,000/QALY - \$75,000/QALY by ESC in March 2014 was likely to be a conservative estimate, particularly in relation to the approach to modelling of loss of response in placebo patients. The PBAC recalled that it had previously indicated an ICER in the range of \$40,000/QALY - \$45,000/QALY would be required to recommend listing. If the ICER of in the range of \$45,000/QALY - \$75,000/QALY in moderate to severe ulcerative colitis was close to this range, the PBAC considered that infliximab would be sufficiently cost-effective to be PBS-listed for the treatment of moderate to severe ulcerative colitis.
- 7.7 The minor resubmission's estimates of PBS usage were unchanged from March 2014 and given that no price reduction was offered in the minor resubmission, the estimates of the financial implications for the PBS also remained unchanged from March 2014. The PBAC had previously considered March 2014 revised estimates that accounted for a higher than expected number of patients accessing maintenance therapy due to the use of a partial Mayo score as opposed to the full Mayo score and the lower number of vials used in paediatric patients than estimated in the March 2014 submission, to be reasonable.
- 7.8 Consistent with the March 2014 recommendation, the PBAC reaffirmed that it did not recommend infliximab be included in the list of PBS medicines for prescribing by nurse practitioners, noting that nurse practitioners are not able to prescribe infliximab for its current PBS-listed indications.
- 7.9 The PBAC noted that this submission is not eligible for an Independent Review.

Outcome:

Recommended

8 Recommended listing

- 8.1 Add new indication (*to be finalised*):

Initial treatment for new patients:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
INFLIXIMAB				
infliximab 100 mg injection, 1 x 100 mg vial	1	0	Remicade	JC

Public Summary Document– July 2014 PBAC Meeting

Category/ Program	S100 – Section 100 (Highly Specialised Drugs) – Private Hospitals (Code HS) S100 – Section 100 (Highly Specialised Drugs) – Public Hospitals (Code HB)
Restriction level:	Authority required (Public/Private Hospital) – WRITTEN ONLY
Episodicity:	---
Severity:	Moderate to severe
Condition:	ulcerative colitis
Indication:	Moderate to severe ulcerative colitis
Treatment phase:	Initial treatment (new patient)
Treatment criteria:	<p>Patient must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Patient must be treated by, or have an appointment to be assessed by, a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years;</p>
Clinical criteria:	<p>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 months or have intolerance necessitating permanent treatment withdrawal;</p> <p>AND</p> <p>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 months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>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 months or have intolerance necessitating permanent treatment withdrawal; OR</p> <p>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;</p> <p>AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR</p> <p>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</p> <p>Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years;</p>
Population criteria:	Patient must be 6 years of age or older;

<p>Prescriber Instructions</p>	<p>Applications for authorisation of initial treatment must be in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:</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]; and</p> <p>(iii) the signed patient acknowledgement.</p> <p>Under no circumstances will telephone approvals be granted for initial authority applications under this restriction, or for treatment that would otherwise extend the initial treatment period.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent Mayo clinic, partial Mayo clinic or PUCAI score must be no more than 1 month old at the time of application.</p> <p>Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score 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.</p> <p>The patient or guardian must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.</p> <p>If treatment with any of the above-mentioned 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 Department of Human Services website (www.humanservices.gov.au).</p> <p>Patients may qualify for PBS-subsidised treatment under this restriction once only.</p>
<p>Administrative Advice</p>	<p><u>NOTE:</u> Special pricing arrangements apply</p>

Balance of supply for initial new patients:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
INFLIXIMAB				
infliximab 100 mg injection, 1 x 100 mg vial	1	0	Remicade	JC

Public Summary Document– July 2014 PBAC Meeting

Category/ Program	S100 – Section 100 (Highly Specialised Drugs) – Private Hospitals (Code HS) S100 – Section 100 (Highly Specialised Drugs) – Public Hospitals (Code HB)
Restriction level:	Authority required (Public/Private Hospital) – Telephone - permitted Authority required (Public/Private Hospital) – Written - permitted
Episodicity:	---
Severity:	Moderate to severe
Condition:	ulcerative colitis
Indication:	Moderate to severe ulcerative colitis
Treatment phase:	Initial treatment – Balance of supply
Treatment criteria:	Patient must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Patient must be treated by, or have an appointment to be assessed by, a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years;
Clinical criteria:	Patient must have received insufficient infliximab therapy under the Initial (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); AND The treatment must provide no more than the balance of up to 3 doses;
Population criteria:	Patient must be 6 years of age or older;
Prescriber Instructions	Authority approval for sufficient therapy to complete a maximum of 3 doses may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 3 doses should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001
Administrative Advice	<u>NOTE:</u> Special pricing arrangements apply

Continuing treatment:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
INFLIXIMAB				
infliximab 100 mg injection, 1 x 100 mg vial	1	0	Remicade	JC

Category/ Program:	S100 – Section 100 (Highly Specialised Drugs) – Private Hospitals (Code HS) S100 – Section 100 (Highly Specialised Drugs) – Public Hospitals (Code HB)
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Public Summary Document– July 2014 PBAC Meeting

Restriction level:	Authority required (Public/Private Hospital) – Telephone - permitted Authority required (Public/Private Hospital) – Written - permitted
Episodicity	----
Severity:	Moderate to severe
Condition:	ulcerative colitis
Indication:	Moderate to severe ulcerative colitis
Treatment phase:	Continuing treatment
Treatment criteria:	Patient must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Patients must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years;
Clinical criteria:	Patient must have 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 a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment this drug if aged 6 to 17 years;
Prescriber Instructions	Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a PUCAI score 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. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Administrative Advice	<u>NOTE:</u> Special pricing arrangements apply

Grandfathered patients (remove 12 months post implementation):

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
INFLIXIMAB				
infliximab 100 mg injection, 1 x 100 mg vial	1	0	Remicade	JC

Category/ Program	S100 – Section 100 (Highly Specialised Drugs) – Private Hospitals (Code HS) S100 – Section 100 (Highly Specialised Drugs) – Public Hospitals (Code HB)
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Restriction level:	Authority required (Public/Private Hospital) – WRITTEN ONLY
Episodicity	----
Severity:	Moderate to severe
Condition:	ulcerative colitis
Indication:	Moderate to severe ulcerative colitis
Treatment phase:	Initial PBS-subsidised treatment of moderate to severe ulcerative colitis in a patient who has previously received non-PBS-subsidised therapy with this drug
Treatment criteria:	<p>Patient must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR</p> <p>Patient must be treated by, or have an appointment to be assessed by, a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years;</p>
Clinical criteria:	<p>Patient must have been receiving treatment with this drug prior to [insert listing start date here]</p> <p>AND</p> <p>Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR</p> <p>Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR</p> <p>Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR</p> <p>Patient must have a documented history of moderate to severe ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available;</p> <p>AND</p> <p>Patient must have a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR</p> <p>Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment this drug if aged 6 to 17 years;</p>
Population criteria:	Patient must be 6 years of age or older;

<p>Prescriber Instructions</p>	<p>Applications for authorisation of initial treatment must be in writing and must include:</p> <ul style="list-style-type: none"> (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following: <ul style="list-style-type: none"> (i) the completed current and baseline 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 signed patient acknowledgement. <p>Under no circumstances will telephone approvals be granted for initial authority applications under this restriction, or for treatment that would otherwise extend the initial treatment period.</p> <p>The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5.p.m. EST Monday to Friday).</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.</p> <p>The patient or guardian must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.</p> <p>Patients may qualify for PBS-subsidised treatment under this restriction once only.</p>
<p>Administrative Advice</p>	<p><u>NOTE:</u> Special pricing arrangements apply</p>

9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

10 Sponsor's Comment

Janssen is pleased that patients will soon be able to access Remicade treatment for their moderate to severe ulcerative colitis under the PBS.