

## 7.18 TOCILIZUMAB

### Injection 162 mg/0.9 mL, pre-filled syringe and pen, Actemra<sup>®</sup>, Roche Products Pty Ltd

#### 1 Purpose of Application

- 1.1 The minor resubmission requested a Section 85, Authority Required (in writing) listing for tocilizumab for the treatment of patients with giant cell arteritis (GCA).
- 1.2 Tocilizumab was deferred by the PBAC for this indication in November 2018. The minor resubmission attempted to address concerns raised in that consideration.

#### 2 Requested listing

- 2.1 The minor resubmission requested the following new listing. Changes since the November 2018 PBAC Public Summary Document (PSD) are underlined>.

Name, Restriction, Manner of administration and form	Max. Qty Packs	Max. QTY Units	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
TOCILIZUMAB					
162 mg/0.9 mL injection, 4 x 0.9 mL pre-filled syringe	1	4	5	\$763.78	Actemra <sup>®</sup> Roche
162 mg/0.9 mL injection, 4 x 0.9 mL pre-filled pen	1	4	5		

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Active
<b>Condition:</b>	Giant cell arteritis
<b>PBS Indication:</b>	Active giant cell arteritis
<b>Treatment phase:</b>	Initial
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Authority Required - In Writing
<b>Treatment criteria:</b>	Patient must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis

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<p><b>Clinical criteria:</b></p>	<p>Patient must have active giant cell arteritis defined as the:</p> <ul style="list-style-type: none"> <li>• presence of clinical signs and symptoms AND ESR <math>\geq</math> 30 mm/hour or CRP <math>\geq</math> 10 mg/L) within the past 6 weeks;</li> <li>OR</li> <li>• presence of clinical signs and symptoms AND active giant cell arteritis confirmed by positive temporal artery biopsy or imaging</li> </ul> <p>AND</p> <p>The treatment must in combination with a tapering course of corticosteroids</p> <p>AND</p> <p>The treatment with this drug for this condition must not exceed a total of 12 months therapy</p>
<p><b>Definitions</b></p>	<p><b>Giant cell arteritis diagnosis criteria</b></p> <p>Clinical signs and symptoms of active giant cell arteritis must be in the absence of any other identifiable cause and must include:</p> <ul style="list-style-type: none"> <li>• Age <math>\geq</math> 50 years,</li> <li>• ESR <math>\geq</math> 30 mm/hour or CRP <math>\geq</math> 10 mg/L at time of diagnosis</li> </ul> <p>AND at least one of the following:</p> <ul style="list-style-type: none"> <li>• Unequivocal cranial symptoms of giant cell arteritis (new-onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia-related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); OR</li> <li>• Symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness</li> </ul> <p>AND at least one of the following:</p> <ul style="list-style-type: none"> <li>• Temporal artery biopsy or <u>ultrasound</u> revealing features of giant cell arteritis; OR</li> <li>• Evidence of large-vessel vasculitis by MR or CT angiography or PET/CT</li> </ul>
<p><b>Administrative Advice</b></p>	<p>Up to a maximum of 12 months of therapy will be reimbursed through the PBS</p> <p>The authority application must be made in writing and must include:</p> <ol style="list-style-type: none"> <li>(1) a completed authority prescription form;</li> <li>(2) a completed Giant Cell Arteritis - Supporting Information Form; and</li> <li>(3) documentation that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR and CRP levels, or positive temporal artery biopsy or imaging within the last 6 weeks;</li> </ol> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>

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<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Authority Required - Telephone
<b>Treatment criteria:</b>	Patient must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis
<b>Clinical criteria:</b>	Patient must have previously received PBS-subsidised treatment with this drug for this condition AND The treatment with this drug for this condition must not exceed a total of 12 months of therapy
<b>Administrative Advice</b>	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

- 2.2 At the November 2018 meeting, the PBAC considered that further work was required around the imaging and biopsy requirements for diagnosis of GCA in the proposed restriction to ensure accurate diagnosis of GCA (Paragraph 2.10, Tocilizumab November 2018 PBAC PSD).
- 2.3 The minor resubmission revised the proposed restriction to specify that the diagnostic criteria for GCA must include either temporal artery biopsy or ultrasound revealing features of GCA; or evidence of large-vessel vasculitis by MR or CT angiography or PET/CT (change underlined). The minor resubmission noted that ultrasound was not part of the inclusion criteria in the GiACTA trial, but claimed that ultrasound has improved reliability and readability versus temporal artery biopsy and improved safety and tolerability versus other imaging techniques (Schmidt, 2018). The resubmission further stated that the most recent European League Against Rheumatism (EULAR) Guidelines (titled the ‘EULAR recommendations for the use of imaging in large vessel vasculitis in clinical practice’) state that “ultrasound of the temporal ± axillary arteries is recommended as the first imaging modality in patients with suspected predominantly cranial GCA”. The guidelines further state that ultrasound should be the primary imaging test in patients with suspected GCA presenting predominantly with cranial symptoms because of a high level of evidence of good test performance, easy access, absence of radiation or other procedural risks and the relative low costs as compared with other modalities (Recommendation 3 from DeJaco, 2018).

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- 2.4 The minor resubmission further stated that expert opinion was that ultrasound is standard practice and should be included in the diagnostic criteria. No further details were provided regarding the how the expert opinion was obtained (for example, what questions were asked, how many clinicians were surveyed and what specialty-types were represented).
- 2.5 The minor resubmission did not address whether the inclusion of ultrasound in the diagnostic criteria would enable detection of GCA with a different severity level to that included in the GiACTA trial (for example, ultrasound may potentially detect less severe disease which could reduce the applicability of the trial results).
- 2.6 The PBAC advised that ultrasound should not be included as part of the diagnostic criteria in the restriction as it was not used in the GiACTA trial inclusion criteria, and the PBAC considered that it is highly operator dependant and is not standard practice at most sites in Australia.
- 2.7 The PBAC noted that the minor resubmission had updated the imaging criteria for evidence of large-vessel vasculitis in line with the wording suggested by the PBAC in November 2018 (i.e. amended to be ‘evidence of large-vessel vasculitis by MR or CT angiography or PET/CT’).
- 2.8 The proposed restriction includes diagnostic criteria that require patients to have had, at the time of initial GCA diagnosis, an erythrocyte sedimentation rate (ESR)  $\geq 30$  mm/hour or c-reactive protein (CRP)  $\geq 10$  mg/L. These thresholds are less stringent than those proposed in the previous submission, which were ESR  $\geq 50$  mm/hour or CRP  $\geq 24.5$  mg/L at diagnosis. The resubmission stated this change was based on clinician advice which included that the “inflammatory marker levels should be lower (blindness in patients occur with low markers)”. However, the newly proposed thresholds do not align with the GiACTA trial inclusion criteria, which required patients to have had a history of ESR  $\geq 50$  mm/hour; if historic ESR was unavailable, a history of CRP  $\geq 24.5$  mg/L was required. The PBAC considered that use of lower levels of inflammatory markers in the PBS restriction, compared with the trial, would reduce the applicability of the trial results. The PBAC advised that the restriction should specify that diagnosis of giant cell arteritis must include a history of ESR  $\geq 50$  mm/hour or CRP  $\geq 24.5$  mg/L (among other factors).
- 2.9 The GiACTA trial and the proposed restriction included two sets of thresholds for inflammatory markers:
- thresholds required at initial diagnosis of GCA, as outlined above; and
  - thresholds to indicate active disease within the previous six weeks (ESR  $\geq 30$  mm/hour or CRP  $\geq 10$  mg/L). The PBAC noted that, in the GiACTA trial, the thresholds to indicate active disease were lower than the inflammatory marker levels required at initial diagnosis, and the PBAC considered that it was appropriate for the restriction to include different thresholds for initial diagnosis versus active disease.

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- 2.10 Consistent with the PBAC’s previous advice, the proposed restriction was updated:
- to be Authority Required (In Writing) for Initial treatment and Authority Required (Telephone) for Continuing treatment. This was consistent with the PBAC’s previous advice that these restriction levels would be required to help mitigate the risk of use beyond 12 months (Paragraph 2.7, Tocilizumab November 2018 PSD).
  - to specify that a maximum of 12 months of tocilizumab will be PBS-subsidised (rather than 52 injections, which would have allowed 24 months of therapy if used fortnightly) (Paragraph 7.5, Tocilizumab November 2018 PBAC PSD).
  - to specify that the patient must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of GCA (Paragraph 2.9, Tocilizumab November 2018 PBAC PSD).

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

### 3 Background

- 3.1 The subcutaneous formulation of tocilizumab was registered on the ARTG on 14 November 2017 for the treatment of GCA in adult patients. Tocilizumab is also TGA registered for use in rheumatoid arthritis (intravenous and subcutaneous formulations), polyarticular juvenile idiopathic arthritis (intravenous formulation), and systemic juvenile idiopathic arthritis (intravenous formulation).
- 3.2 Table 1 presents a summary of the matters of concern from the November 2018 PBAC meeting.

**Table 1: Summary of matters of concern from the November 2018 PBAC meeting**

Component	Matter of concern (November 2018 Minutes)	How the resubmission proposed to address it
PBS Restriction	Expert advice required around imaging and biopsy requirements for GCA diagnosis (Para 7.16). The PBAC also provided suggested wording around imaging in the diagnostic criteria (Section 2)	Added ultrasound in the diagnosis of GCA involving the cranial arteries. Proposed restriction was updated to include PBAC’s suggested wording around imaging.
Financial estimates	The financial estimates should account for the proportion of patients who could use fortnightly dosing (Para 7.16)	Assumes ■% of patients could use fortnightly dosing (versus ■% in the previous submission).
Financial estimates	- An incidence rate of ■ per 100,000 persons > 50 years should be used. - The RSA caps should be informed by a compliance rate of 85% and a reduced uptake rate (Para 7.13).	Addressed. - Incidence rate reduced from 12.73 to 9.6 per 100,000 persons > 50 years. - The compliance and uptake rates were both reduced from ■% to ■%.
Risk-share arrangement	An RSA proposal with hard caps should be provided (Para 7.16)	Addressed.

Source: Tables 1 and 2 of the minor resubmission.

PBAC= Pharmaceutical Advisory Committee; PSD= Public Summary Document; RSA= risk sharing arrangement

## 4 Consideration of the evidence

### *Sponsor hearing*

4.1 There was no hearing for this item as it was a minor submission.

### *Consumer comments*

4.2 The PBAC noted that no consumer comments were received for this item.

### *Interpretation of clinical evidence*

4.3 As a minor submission, no new clinical evidence was provided in the submission.

## 5 Estimated PBS usage & financial implications

5.1 At its November 2018 meeting, the PBAC considered that “based on the data presented, there was limited difference in efficacy between weekly versus fortnightly dosing of tocilizumab.” (Paragraph 7.4, Tocilizumab November 2018 PBAC PSD). The data presented included the GiACTA trial, which found that the proportion of patients in sustained remission at 52 weeks (the primary outcome) was 56% and 53% for patients in the tocilizumab weekly and fortnightly arms, respectively (both were in combination with a 26 week corticosteroid taper). As such, the November 2018 PBAC considered that “the financial estimates should be updated to account for the proportion of patients who could use fortnightly dosing” and that an RSA with hard caps would be required (Paragraph 7.16, Tocilizumab November 2018 PBAC PSD).

5.2 Given there is a lack of evidence that weekly administration provides superior efficacy versus fortnightly administration, it may not be appropriate for the Commonwealth to pay for weekly administration in those patient groups who may be appropriate for fortnightly administration, i.e. patients whose active disease is under control, newly diagnosed patients and patients who cannot self-administer the subcutaneous injection.

5.3 The minor resubmission stated that advice received from clinicians was that “no patients would be initiated on a fortnightly dose taking into account clinical context and patient concerns around the risk of relapse and clinical sequelae from a disease flare, including vision loss”. The resubmission also stated that fortnightly dosing is feasible in patients with good disease control, but suggested that patients may not be down-titrated to fortnightly dosing if funded access to weekly dosing were available.

5.4 To help address the PBAC’s previous concerns, the minor resubmission updated the financial estimates to incorporate █% of patients using the fortnightly dosing regimen, which it noted was equivalent to █% of patients using weekly dosing for 6 months followed by fortnightly dosing for the latter 6 months.

### Other changes to the financial estimates

5.5 Compared with the previous submission, four other changes were made to the

financial estimates:

- The incidence was reduced from 12.73 to [REDACTED] per 100,000 persons aged > 50 years, consistent with PBAC’s previous advice. The revised incidence rate was based on a sensitivity analysis provided in the November 2018 pre-PBAC response which had used an incidence rate [REDACTED] that reported in Dunstan 2014 (resulting in an incidence of [REDACTED] per 100,000 persons aged >50 years). The previous submission had stated “discussion with Roche’s advisory board supported the incidence being considered low and consensus was that a more realistic estimate was to “[REDACTED]” the incidence reported by Dunstan.” (Paragraph 7.65, Tocilizumab November 2018 PBAC PSD). The PBAC considered that the incidence of [REDACTED] per 100,000 persons aged > 50 years, as used in the minor resubmission, was reasonable.
  - The compliance rate was reduced from [REDACTED]% in the previous submission to 85% (based on usage in the trial), consistent with the PBAC’s previous advice (and consistent with the value used in the previous pre-PBAC response).
  - The uptake rate was reduced from 100% to [REDACTED]%, in response to the PBAC’s previous advice that a reduced uptake rate should be used. The minor resubmission stated the revised rate was based on clinician advice.
  - The price of tocilizumab was reduced (from an AEMP of \$852.28 in the previous submission to \$681.82) consistent with the current price of tocilizumab in rheumatoid arthritis (following a [REDACTED]% statutory price reduction in the rheumatoid arthritis indication).
- 5.6 The net cost to the PBS/RPBS/MBS, as estimated in the minor resubmission, is shown in Table 1.

**Table 2: Estimated utilisation and cost to the PBS/RPBS of listing tocilizumab for GCA**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Incident GCA patients	█	█	█	█	█	█
“Prevalent” patients <sup>a</sup>	█	█	█	█	█	█
Total treated patients (█ % uptake)	█	█	█	█	█	█
Scripts dispensed (assumes █ % fortnightly dosing, 85% compliance)	█	█	█	█	█	█
Cost of tocilizumab scripts	█	█	█	█	█	█
Patient copayments (\$20.56)	█	█	█	█	█	█
<b>Net cost to PBS/RPBS (Proposed RSA cap)</b>	█	█	█	█	█	█
MBS costs (6.5 tests per patient; \$17.70 per test)	█	█	█	█	█	█
<b>Net cost to PBS/RPBS/MBS</b>	█	█	█	█	█	█
<b>Previous submission (per November 2018 Minutes)</b>						
Treated patients	█	█	█	█	█	█
Tocilizumab scripts	█	█	█	█	█	█
<b>Net cost to PBS/RPBS</b>	█	█	█	█	█	█

Source: Actemra\_Section 4\_minor resubmission.xlsx of the resubmission; Tables 3 and 4 of the minor resubmission

Abbreviations: GCA, giant cell arteritis; PBS, Pharmaceutical Benefits Scheme; RPBS, Repatriation Pharmaceutical Benefits Scheme

<sup>a</sup> Relapsed incident patients

5.7 The minor resubmission estimated that the net cost to the PBS/RPBS (which forms the basis for the proposed RSA cap) would be less than \$10 million in Year 1 decreasing to less than \$10 million in Year 6 with a total of \$30 - \$60 million over the first six years of listing. This compares with an estimated cost of \$60 - \$100 million over six years in the previous submission, and \$60 - \$100 million over six years in the previous pre-PBAC response (Paragraph 6.64, Tocilizumab November 2018 PBAC PSD).

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

### Quality Use of Medicines

5.8 The PBAC previously considered that, “based on the limited longer-term data available, there were high rates of relapse in patients who initially responded to 12 months of tocilizumab treatment.... The PBAC considered that the large number of flares in the post-treatment period suggests that tocilizumab may suppress rather than prevent relapse. The PBAC considered that it would be important for the sponsor to ensure there are Quality Use of Medicines initiatives to help manage the expectations of clinicians and patients.” (Paragraph 7.10, Tocilizumab November 2018 PBAC PSD). No further information was provided in the minor resubmission to address the PBAC’s previous concerns regarding the high rates of relapse and the expectations of clinicians and patients.

5.9 The PBAC recalled that, based on data provided in the previous submission, the open-label extension of the GiACTA trial found that, of patients who were in remission after 12 months of treatment, flares were subsequently observed in 8/24 (33%) of the tocilizumab weekly group, and 8/11 (73%) of the tocilizumab fortnightly group. The PBAC further recalled that it had previously noted that “similar rates of relapse (11/20

(55%) were observed in a Phase 2 study of tocilizumab in GCA (albeit a different dose of tocilizumab was used) (Adler 2016)” (Paragraph 7.10, Tocilizumab November 2018 PBAC PSD).

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

## **6 Financial Management – Risk Sharing Arrangements**

- 6.1 The PBAC previously considered that an RSA with a [REDACTED] % rebate above the caps would be required given the uncertain GCA incidence rate and the potential for use outside the proposed restriction (Paragraph 7.15, Tocilizumab November 2018 PBAC PSD).
- 6.2 The minor resubmission acknowledged that there is uncertainty regarding the incidence of GCA and potential for use outside the restriction, and stated it was willing to agree to an RSA with a [REDACTED] % rebate for any PBS expenditure exceeding the cap outlined in Table 2.
- 6.3 The minor resubmission further claimed that uncertainty exists regarding the timing of when patients may initiate therapy and requested the RSA caps be based on cumulative estimates, not yearly estimates (i.e. an expenditure cap rollover arrangement, where expenditure not exceeded in a particular year would be rolled over to the subsequent year to inform capped expenditure in that latter year). It was not considered that it is not appropriate for RSA caps to be cumulative.

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

## **7 PBAC Outcome**

- 7.1 The PBAC recommended the Authority Required listing of tocilizumab for the treatment of patients with giant cell arteritis (GCA). The PBAC considered that the minor resubmission had adequately addressed its concerns from November 2018 (when the Committee had deferred making a recommendation) by revising the restriction and the financial estimates and including an RSA proposal.
- 7.2 The PBAC is satisfied that tocilizumab provides, for some patients, a significant improvement in efficacy over standard of care.
- 7.3 The PBAC reiterated its previous advice that there is a high unmet clinical need for effective treatments for GCA particularly given the adverse events associated with corticosteroids in this population who are often older patients with comorbidities, and the limited treatment options available.
- 7.4 The PBAC noted that the proposed restriction was updated to include the suggested wording around imaging of large-vessel vasculitis from the November 2018 PBAC PSD. The PBAC considered this was appropriate.
- 7.5 The PBAC advised that ultrasound should not be included as part of the diagnostic criteria in the restriction as it was not used in the GiACTA trial inclusion criteria, and the PBAC considered that it is highly operator dependant and is not standard practice

at most sites in Australia.

- 7.6 The PBAC noted that the financial estimates were revised to incorporate an assumption that ■% of patients would use fortnightly, rather than weekly dosing. The PBAC considered this was appropriate in the context of these estimates being used to implement an RSA with a 100% rebate above the subsidy caps, and given there is a lack of evidence that weekly administration provides superior efficacy versus fortnightly administration.
- 7.7 The PBAC noted that that the financial estimates were also revised: to reduce the incidence rate from 12.73 to ■ per 100,000 persons aged > 50 years; to reduce the compliance and uptake rates; and to reduce the price of tocilizumab consistent with the current price of tocilizumab in rheumatoid arthritis. The PBAC considered that these changes were appropriate.
- 7.8 The PBAC noted that the resubmission proposed an RSA with a ■% rebate above the caps and considered this was appropriate given the uncertain GCA incidence rate and the potential for use outside the proposed restriction. The PBAC did not consider that roll-over of financial caps to future years is appropriate, given that estimates are prepared on a yearly basis, and that such rollover would reintroduce a high level of uncertainty.
- 7.9 The PBAC requested that DUSC undertake a 24 month predicted versus actual review of the utilisation of tocilizumab in this indication.
- 7.10 The PBAC remained concerned about the high rates of relapse in patients who initially responded to 12 months of tocilizumab treatment (as outlined in Paragraph 5.9), and considered that the sponsor should provide longer-term follow up data from GiACTA (and its extension studies) regarding the risk of relapse following tocilizumab treatment. The PBAC requested that this be provided as part of the predicted versus actual review.
- 7.11 The PBAC recommended that tocilizumab, in this indication, should not be treated as interchangeable on an individual patient basis with any other drugs.
- 7.12 The PBAC advised that tocilizumab is not suitable for prescribing by nurse practitioners.
- 7.13 The PBAC recommended that the Early Supply Rule should apply.
- 7.14 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## **8 Recommended listing**

Add new listing:

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<b>Clinical criteria:</b>	Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND Patient must have ESR $\geq$ 30 mm/hour within the past 6 weeks; OR Patient must have CRP $\geq$ 10 mg/L within the past 6 weeks; OR Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging AND Patient must have had a history of ESR $\geq$ 50 mm/hour or CRP $\geq$ 24.5 mg/L at diagnosis AND Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis AND The treatment must in combination with a tapering course of corticosteroids; AND The treatment with this drug for this condition must not exceed a total of 12 months therapy
<b>Population criteria</b>	Patient must be aged 50 years or older
<b>Prescriber instruction</b>	Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new-onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia-related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.

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<b>Prescriber instructions</b>	The authority application must be made in writing and must include: (1) a completed authority prescription form; (2) a completed Giant Cell Arteritis - Supporting Information Form; and (3) documentation that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR and CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; (4) documentation that the patient has been diagnosed with giant cell arteritis
<b>Administrative advice</b>	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.  Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services 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 Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>  Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001  No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.

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<b>Administrative Advice</b>	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.  Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised.			

## 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

The sponsor had no comment.