6.06 ANAKINRA
Injection, 100 mg in 0.67 mL single use pre-filled syringe
Kineret®, A.Menarini Australia Pty Ltd

1 Purpose of Application

1.1 The minor submission requested an amendment of the PBS listing of anakinra from Authority Required (STREAMLINED) to Authority Required for treatment of patients with moderate to severe cryopyrin associated periodic syndromes (CAPS).

2 Requested listing

2.1 The submission requested a change of the restriction level of the current restriction from Authority Required (STREAMLINED) to Authority Required. No changes to the existing restriction wording were requested.

For more detail on PBAC's view, see section 5 "PBAC outcome."

3 Background

3.1 Anakinra is TGA registered for:

- The treatment of active adult rheumatoid arthritis in patients who have inadequate response to one or more other Disease Modifying Anti Rheumatic Drugs (DMARDs);
- In adult and paediatric patients for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) including Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA), Muckle-Wells Syndrome (NWS), and Familiar Cold Autoinflammatory Syndrome (FCAS); and
- The treatment of active Systemic Juvenile idiopathic Arthritis (SJIA) in patients 2 years and above who have failed to respond adequately to non-biological DMARDs.

3.2 The PBAC recalled that anakinra was recommended for patients with moderate to severe CAPS under the Authority Required (STREAMLINED) Section 100 Highly Special Drugs schedule at the November 2014 PBAC meeting.

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.

Estimated PBS usage & financial implications

4.3 The minor submission did not present any information regarding estimated PBS usage or financial implications. However, the submission expected that the change in restriction level would prevent the use of the drug outside of the current restriction, and hence lower the overall use of anakinra as subsidised by the PBS.

4.4 Overall, the submission's assumption of use of anakinra outside the current restriction may not be reasonable as the submission did not provide any evidence to support this claim. The PBAC noted that, as indicated by the DUSC Secretariat, a small number of patients may be using higher than expected doses of anakinra, which may contribute to higher expenditure.

For more detail on PBAC's view, see section 5 "PBAC outcome."

5 PBAC Outcome

5.1 The PBAC did not recommend amending the Authority Required (STREAMLINED) listing for anakinra to an Authority Required listing for the treatment of patients with moderate to severe cryopyrin associated periodic syndromes (CAPS).

5.2 The PBAC noted that the Sponsor presented utilisation data for anakinra in the first 21 months of listing, and claimed that the number of scripts used was higher than anticipated. Based on these utilisation data and the sponsor's assumption of leakage to patients with other conditions the sponsor requested a change in restriction level to Authority Required.

5.3 The PBAC did not consider that the claim of use outside of the current restriction was reasonable as no evidence was provided to support this claim. Based on data provided by the DUSC Secretariat, the PBAC noted that the number of patients was similar to expected in Year 1 of listing and slightly higher than expected based on available data for year 2. However, the number of prescriptions has been lower than expected as outlined in the following table.

Table 1: Predicted vs. actual prescriptions of anakinra

Year		Year 1	Year 2*
Patients	Predicted	[redacted]	[redacted]
	Actual	[redacted]	[redacted]
Packs	Predicted	[redacted]	[redacted]
	Actual	492	534

Note: Year 2 includes nine months of the year (June 2016 to February 2017)

5.4 The PBAC previously recommend the listing of anakinra for patients with moderate to severe CAPS under the Authority Required (STREAMLINED) Section 100 Highly Special Drugs (HSD) schedule at the November 2014 PBAC meeting. The PBAC recalled that a Risk Sharing Arrangement was also recommended at the time of recommendation to manage any risk of leakage into rheumatoid arthritis and mild forms of CAPS (such as Familiar Cold Autoinflammatory Syndrome) (Anakinra public summary document, November 2014 PBAC Meeting). The PBAC noted that the cap established as part of the Risk Sharing Arrangement [redacted] indicating that the current restriction appears appropriate.

5.5 The PBAC considered that the submission provided no clinical basis to change the level of authority, and therefore increase the administrative burden for prescribers, for anakinra. The PBAC considered the current restriction level is appropriate. The PBAC recommend that the Department should remain in communication with the sponsor to monitor the utilisation of anakinra.

5.6 The PBAC noted that this submission is not eligible for an Independent Review as an Independent Review is not available in response to a request to modify an existing listing.

Outcome:

Rejected

6 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.

7 Sponsor's Comment

The sponsor had no comment.