

## 5.26 TOCILIZUMAB

### Injection 162 mg in 0.9 mL auto-injector, subcutaneous injection Actemra® ACTPen, Roche Products Pty Ltd

#### 1 Purpose of Application

- 1.1 The minor submission requested an Authority Required listing for an auto-injector presentation for subcutaneously (SC) administered tocilizumab for the treatment of severe active rheumatoid arthritis (RA) in adult patients.
- 1.2 The submission intends for the auto-injector presentation to replace the currently listed pre-filled syringe presentation, particularly in those patients who have difficulty self-administering the pre-filled syringe.

#### 2 Requested listing

- 2.1 The submission requested listing for the new pre-filled pen form of tocilizumab with the same restriction as the existing pre-filled syringe for adults with severe active RA under the same conditions as the existing pre-filled syringe listings. Given the size and complexity of the restrictions, they have not been reproduced in full.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
TOCILIZUMAB 162 mg/0.9 mL injection, 4 × 0.9 mL auto-injector	1	3(initial) 5(continuing)	\$953.23	ACTEMERA® ACTPen	Roche Products Pty Ltd

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

#### 3 Background

- 3.1 The auto-injector presentation of tocilizumab was TGA registered on 15 February 2018 for the same indications for which other presentations of tocilizumab are currently registered for:
  - The treatment of moderate to severe active RA in adult patients in combination with methotrexate (MTX) or other non-biological disease-

modifying anti-rheumatic drugs (DMARDs) in case of either an inadequate response or intolerance to previous therapy with one or more DMARDs.

- Tocilizumab SC is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients with poor prognostic factors in combination with MTX in those not previously treated with MTX.
- In the two groups of patients above, tocilizumab SC can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

- 3.2 The SC pre-filled syringe presentation was recommended for PBS listing as monotherapy or in combination with MTX, for patients with prior DMARD inadequate response, on a cost-minimisation basis with other bDMARDs by the PBAC in March 2016.

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

## **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.

### ***Clinical claim***

- 4.3 The submission claimed that auto-injector devices are widely preferred by clinicians and patients, and this new presentation of tocilizumab would provide a more convenient administration option over the pre-filled syringe presentation of tocilizumab. The submission did not provide any evidence to support this claim.
- 4.4 Based on a market share analysis of 10% Medicare Sample data in 2016 and 2017, the sponsor claimed that more than half of patients who received SC bDMARD treatment were administered with pre-filled pens compared to pre-filled syringe presentations.
- 4.5 The pre-PBAC response provided a similar market share analysis with data from March 2015 to March 2018. The result also indicated that the majority of patients were administered treatment with auto injector delivery devices. Neither analysis was independently validated.

### **Estimated PBS usage & financial implications**

- 4.6 The minor submission estimated there to be no financial implications to the PBS as the submission expected the new presentation would substitute for the existing pre-filled syringe presentation only.

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

## **5 PBAC Outcome**

- 5.1 The PBAC recommended the Authority Required listing of a new auto-injector form of subcutaneous (SC) tocilizumab (162 mg in 0.9 mL) for the treatment of severe active rheumatoid arthritis (RA) in adult patients under the same conditions as the currently listed pre-filled syringe.
- 5.2 The PBAC noted that the sponsor indicated its commitment to mitigate the risk in consumer confusion due to administration differences with the device. The submission included a TGA letter that confirms that the sponsor has agreed to insert instructions for use within the packaging that will help mitigate the risk of patient confusion and improper administration. In the pre-PBAC response, the sponsor also specified that a comprehensive home care package, patient training and customer support programs would be introduced alongside the launch of tocilizumab SC auto-injector in Australia.
- 5.3 The PBAC considered that the 162 mg in 0.9 mL pre-filled syringe and auto-injector forms of tocilizumab should not be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) due to the differences in the administration techniques between the devices.
- 5.4 The PBAC noted that the Early Supply Rule should apply to the continuing treatment phase listing as it currently applies to the existing pre-filled syringe presentation for tocilizumab, similar to other subcutaneous bDMARD presentations.
- 5.5 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

### **Outcome:**

Recommended

## 6 Recommended listing

6.1 Add new item – same restrictions for item 10951J (initial) and 10954M (continuing)

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## 7 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.

## 8 Sponsor's Comment

The sponsor had no comment.