5.15 ABATACEPT
125mg/mL injection, 4 x 1mL autoinjector, Orencia®, Bristol-Myers Squibb Australia Pty Ltd

1 Purpose of application

1.1 The minor submission sought to request an Authority Required listing for an autoinjector presentation for the treatment of severe active rheumatoid arthritis.

2 Requested Listing

2.1 The submission requested the same restriction wording as the current listing for abatacept 125 mg/mL injection, 4 x 1 mL pre-filled syringes, with a minor edit to the Administrative Note concerning abatacept patients, as shown below:

‘Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes autoinjector, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.’

Initial treatment

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
ABATACEPT abatacept 125 ng in 1 mL single dose, 4 x 1 mL pre-filled autoinjector	1	3	$1743.21	Orencia BQ

Continuing treatment

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
ABATACEPT abatacept 125 ng in 1 mL single dose, 4 x 1 mL pre-filled autoinjector	1	5	$1743.21	Orencia BQ

3 Background

3.1 The autoinjector presentation for abatacept had not been considered by PBAC previously.

3.2 Two presentations of abatacept are currently reimbursed on the PBS for the treatment of severe active rheumatoid arthritis. A Section 100 listing for abatacept 250 mg injection for intravenous infusion and a Section 85 listing for the 125 mg/mL (pre-filled syringe) injection.

3.3 Abatacept 125 mg/mL pre-filled autoinjector was TGA registered on 2 July 2015.

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 Trials

4.3 As a minor submission, no clinical trials were presented.

5 Pricing considerations

5.1 The submission requested the price for abatacept autoinjector to be the same as the current price for the pre-filled syringe presentation, currently at $1,743.21 (DPMQ).

5.2 Although not a matter for PBAC, it was noted that this listing would trigger section 99ACB of the National Health Act 1953.

6 PBAC Outcome

6.1 The PBAC recommended the listing of abatacept 125 mg/mL injection, 4 x 1 mL autoinjector for the treatment of severe rheumatoid arthritis, noting that the requested Section 85 Authority Required listing, and the proposed maximum quantity and number of repeats are consistent with the current listing of the 125 mg/mL pre-filled syringe (item codes 1220F and 1221G) for initial and continuing treatment phases.

6.2 The PBAC recommended that the Safety Net 20 Day Rule should apply to the continuing treatment phase listing as it currently applies to abatacept 125mg/mL injection.

6.3 The PBAC recommended that abatacept 125mg/mL injection, 4 x 1mL autoinjector and abatacept 125mg/mL injection, 4 x 1mL pre-filled syringe should be considered equivalent for the purposes of substitution ('a' flagged in the Schedule), given that the injection volume of both delivery device is equivalent to 125 mg of abatacept.

6.4 The PBAC noted that a flow-on change will be required to the Administrative Notes for the following drugs listed for treating rheumatoid arthritis:

- adalimumab
- certolizumab
- etanercept
- golimumab
- infliximab
- rituximab
- tocilizumab
- tofacitinib
- abatacept

6.5 Therefore, to ensure consistency between listings, the PBAC recommended that the Administrative Note for all listings – including for the autoinjector – should be worded as below:

'Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.'

Outcome:
Recommended

7 Recommended listing

7.1 Recommended new listing, with the same restriction wording as the current listings for abatacept 125 mg/mL injection, 4 x 1 mL pre-filled syringes, but including a minor amendment to the Administrative NOTE as per paragraph 6.5 above.

Initial treatment

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
ABATACEPT abatacept 125 ng in 1 mL single dose, 4 x 1 mL pre-filled autoinjector	1	3	Orencia BQ

Continuing treatment

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer
ABATACEPT abatacept 125 ng in 1 mL single dose, 4 x 1 mL pre-filled autoinjector	1	5	Orencia BQ

7.2 Amend NOTE for listings for the below drugs, as per paragraph 6.5 above.

- adalimumab
- certolizumab
- etanercept
- golimumab
- infliximab
- rituximab
- tocilizumab
- tofacitinib
- abatacept

7.3 Add schedule equivalence NOTE:

Pharmaceutical benefits that have the form abatacept 125 mg/mL injection syringe and pharmaceutical benefits that have the form abatacept 125 mg/mL autoinjector are equivalent for the purposes of substitution.

8 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.

9 Sponsor's Comment

The Sponsor had no comment.