14.17 AURANOFIN
Capsule 3 mg,
Ridaura®, Boucher and Muir Pty Ltd

1 Purpose of Application

1.1 To request listing of a new capsule form of auranofin.

1.2 The sponsor requested listing of this substitute product as a replacement form of the currently listed auranofin due to a shortage of supply of the later.

2 Requested listing

2.1 The sponsor requested the same listing as the current tablets:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	DPMQ	Proprietary Name and Manufacturer
AURANOFIN 3 mg capsule, 60	1	5	$[redacted]	Ridaura Boucher and Muir Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐Midwives

For more detail on PBAC's view, see section 4 "PBAC outcome."

3 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Current situation

3.3 The sponsor advised that it was unable to guarantee supply of the currently listed auranofin (PBS item 1095P or 10932J).

3.4 The sponsor arranged to supply an alternative product, also branded as Ridaura®, which is considered by the Therapeutic Goods Administration as substitutable for the Australian registered product, for eighteen (18) months under Section 19A of the *Therapeutic Goods Act 1989*. This replacement product is presented in a different form to the currently listed product (a capsule, compared to a tablet), necessitating a new listing on the PBS.

3.5 The sponsor advised that the current tablets will be unavailable from 1 July 2017.

3.6 The PBAC recalled the correspondence from the Australian Rheumatology Association (ARA), considered at the November 2016 PBAC meeting, sent in response to the PBAC's request for advice regarding the ongoing PBS listing of auranofin tablets. The correspondence acknowledged that the clinical usage of auranofin has declined since the development of newer and more efficacious disease-modifying anti-rheumatic drugs (DMARDs); however, auranofin has been shown to have a small clinically and statistically significant benefit on disease activity in some patients with rheumatoid arthritis, particularly those with early or mild disease. The correspondence also noted that auranofin can have a role in treating patients who have had a sub-optimal response to methotrexate, and that it is a cost-effective alternative to biologic DMARDs.

Estimated PBS usage & financial implications

3.7 The minor submission stated there would be a net cost to the PBS listing, however the size of this cost was not calculated in the submission. The submission estimated a script volume of [redacted] scripts per year based on the previous year's script volumes.

3.8 Based on the script volume in the submission and the difference in the requested DPMQ over the currently listed form, the Secretariat has estimated a cost to the PBS as below.

Table 1: Estimated net cost to the PBS for auranofin listing change

	2017	2018
Projected net cost of new listing		
Scripts	[redacted][1]	[redacted]
Proposed DPMQ	$[redacted]	$[redacted]
Cost to PBS[2]	$[redacted]	$[redacted]
Projected net costs of displaced medicines		
Scripts	[redacted][1]	[redacted]
Current DPMQ	237.48	237.48
Cost to PBS[2]	$[redacted]	$[redacted]
Overall net cost to the PBS		
Cost to PBS[2]	**$[redacted]**	**$[redacted]**

[1]projected script volume halved for 2017.
[2]projected costs have not been adjusted to take into account any co-payments.

3.9 The redacted table shows that the net cost to the PBS would be less than $10 million.

For more detail on PBAC's view, see section 4 "PBAC outcome."

4 PBAC Outcome

4.1 The PBAC recommended the temporary listing of a capsule form of auranofin on the PBS on the basis of clinical need.

4.2 The PBAC recommended that the new listing should be consistent with that for the currently listed auranofin product in terms of restriction, maximum quantities and repeats.

4.3 The PBAC considered that there is a clinical need for the supply of this medicine to be maintained on the PBS. The PBAC further considered that the listing should remain during the validity of the Section 19A approval by the TGA. For a longer term listing of the product, a further submission to the PBAC would be required.

Outcome:

Recommended

5 Recommended listing

5.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
AURANOFIN 3 mg capsule, 60	1	5	Ridaura	Boucher and Muir Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☒ Medical Practitioners ☒ Nurse practitioners ☐ Optometrists ☐ Midwives

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.