

6.09 PROGESTERONE, Pessary 200 mg, Oriprio[®], Orion Laboratories Pty Ltd.

1 Purpose of Submission

- 1.1 The Category 4 submission requested an increase in the maximum quantity from 30 pessaries (2 packs) to 45 pessaries (3 packs) and a reduction in the number of repeats from 5 to 3 for the PBS-listed progesterone 200 mg pessary (Oriprio[®]) for the prevention of preterm birth.
- 1.2 The submission has made the request in the context of discrepancies between the PBS listings for Oriprio and another brand of progesterone (Utrogestan[®]), in terms of maximum quantities per script. The submission requested the PBS listings for the two medicines to provide a similar number of doses (units) with the same number of repeats, in order to align the number of patient co-payments.

2 Background

Registration status

- 2.1 Oriprio received TGA approval for use in women at risk of preterm birth in singleton pregnancies on 12 November 2019. The TGA approved indication is: “For the prevention of preterm birth in singleton pregnancies at risk due to shortened cervix (midtrimester sonographic cervix ≤ 25 mm) and/or where there is a history of spontaneous preterm birth.”

Previous PBAC consideration

- 2.2 Oriprio was recommended for the prevention of preterm birth by the PBAC at its November 2020 meeting (and was listed on the PBS from 1 June 2021 for this indication).
- 2.3 At its November 2020 meeting, the PBAC recommended Utrogestan for the same indication (which was listed on the PBS from 1 July 2021).
- 2.4 The PBAC’s recommendation for Oriprio was based on, among other matters, its assessment that the cost-effectiveness of Oriprio would be acceptable if it were cost-minimised against Utrogestan (paragraph 7.1, Oriprio Public Summary Document (PSD), November 2020 PBAC meeting).
- 2.5 At the time, the PBAC noted that there were no other pharmacologic treatments prescribed to reduce the risk of preterm birth, and that there is a clinical need for

prevention of preterm birth in at-risk women. The PBAC noted this was supported by the consumer comments received for this submission (paragraph 7.3, Oriprio PSD, November 2020 PBAC meeting).

- 2.6 The PBAC considered that the price of Oriprio should be no more than for Utrogestan. The equi-effective doses are: one 200 mg Oriprio pessary and one 200 mg Utrogestan soft capsule (paragraph 7.10, Oriprio PSD, November 2020 PBAC meeting).

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

3 Requested listing

- 3.1 The submission requested amending the maximum quantity and number of repeats as follows.

MEDICINAL PRODUCT, medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
PROGESTERONE progesterone 200 mg pessary, 15	12465C	2 3	30 45	5 3	Oriprio

- 3.2 The current Oriprio restriction for prevention of preterm birth provides a maximum quantity of 2 packs, which allows for 30 days (1 month) of therapy (2 × 15 pessaries), and 5 repeats allows for 6 months of therapy (or approximately 6.4 months based on 28 days/month). The Oriprio Product Information (PI) states that dosage of progesterone for this indication is 200 mg daily (at night), and treatment can be initiated at 16 weeks and go through to 36 weeks or delivery (up to 24 weeks of treatment).
- 3.3 The current Utrogestan restriction for prevention of preterm birth provides a maximum quantity of 1 pack of 42 capsules and 3 repeats, which allows for the maximum recommended duration of treatment. Each prescription allows for approximately 6 weeks of therapy. Treatment is initiated during the second trimester (16-24 weeks gestation) and is to be continued to the end of gestation. The requested amount, including the 3 repeats, provides for 24 weeks of treatment (equivalent to 5.6 months based on 30 days/month, or 6 months based on 28 days/month). Like Oriprio, the Utrogestan PI states that the usual dose is 200 mg/day, and that treatment is to be continued until the end of the 36th week of gestation or until delivery.
- 3.4 Currently, both the Oriprio and Utrogestan (prevention of preterm birth) listings provide for roughly the same total duration of therapy.
- 3.5 The requested change for Oriprio would provide a maximum quantity of 45 pessaries (compared to 42 pessaries for Utrogestan). Each prescription would therefore supply approximately 6-7 weeks of therapy (as opposed to the current 1 month of therapy).

However, the total number of pessaries (45 x 4 = 180) remains the same as the current listing (30 x 6 = 180), and would still provide for approximately 6 months of therapy in total.

- 3.6 In accordance with the PBAC Guidelines Version 5.0 , the maximum quantity and number of repeats should account for whether the medicine is an acute-use therapy (such that the requested maximum quantity/amount is consistent with the likely use of the proposed medicine for a normal course of therapy), or a chronic-use therapy (such that maximum quantity/amount is consistent with the likely use of the proposed medicine for one month of therapy between each dispensing by the pharmacist, and that the number of repeats (usually) permits six months of therapy between each prescription). The PBAC Guidelines state that any deviations from this general approach should be justified (e.g. to minimise wastage or to facilitate intermittent therapy).

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.

Consumer Comments

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

Co-payment considerations

- 4.3 The requested amendment for a maximum quantity of 45 pessaries with 3 repeats for Oriprio would reduce the number of patient co-payments from 6 to 4. Currently, the total co-payment costs for Oriprio is \$247.80 for 6 months of treatment (general patient) compared with \$165.20 for a general patient on Utrogestan.
- 4.4 The difference in co-payments are summarised in Table 1.

Table 1: Patient co-payment costs of Oriprio versus Utrogestan (6 months of treatment)

	Tx duration / Script	Scripts / 6 months	Co-payment	
			General patients	Concessional patients
Oriprio	4 weeks	6	\$247.80	\$39.60
Utrogestan	6 weeks	4	\$165.20	\$26.40
Difference	2 weeks less / script	2	\$82.60	\$13.20

Source: Submission body

Tx = Treatment

Estimated PBS utilisation and financial implications

- 4.5 The submission used an epidemiological approach for the utilisation and financial estimates, and stated that the market has not been fully established. The calculations and assumptions used in the November 2020 PBAC submission were also applied in this submission.
- 4.6 The weighted AEMP of Oriprio remains unchanged (\$35.40). The increased maximum quantity results in a DPMQ of \$126.97 (increased from \$88.20). The PBAC considered the increased in DPMQ appropriate in the context of its previous recommendation, where it considered that the price of Oriprio should be no more than for Utrogestan. The equi-effective doses are: one 200 mg Oriprio pessary and one 200 mg Utrogestan soft capsule (paragraph 7.10, Oriprio PSD, November 2020 PBAC meeting).
- 4.7 Based on the requested amendments to the Oriprio (prevention of preterm birth) listing, the submission estimated there would be a net cost to the PBS/RPBS of \$0 to < \$10 million over six years. The loss in average co-payments per patient (\$38.43) offsets the save from the reduction in DPMQ per patient (-\$13.27). This results in a net cost per patient of \$25.16 and hence the net cost to the PBS/RPBS of \$0 to < \$10 million over six years.

Table 2: Estimated use and financial implications

	Year 1 (2022)	Year 2 (2023)	Year 3 (2024)	Year 4 (2025)	Year 5 (2026)	Year 6 (2027)
New listing						
Total number of scripts	■ ¹	■ ¹	■ ¹	■ ²	■ ²	■ ²
Costs of Oriprio to PBS/RPBS (less patient co-payments)	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵
Affected listing						
Total number of scripts	- ■ ²	- ■ ³	- ■ ³	- ■ ⁴	- ■ ⁴	- ■ ⁴
Cost of Oriprio to PBS/RPBS (less patient co-payments)	- ■ ⁵	- ■ ⁵	- ■ ⁵	- ■ ⁵	- ■ ⁵	- ■ ⁵
Estimated net financial implications						
Net cost to PBS/RPBS	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Submission utilisation and cost model workbook - Sheet 3a. Scripts proposed, 4a. Scripts-affected; Table 21: Net cost to the government of Oriprio.

The redacted values correspond to the following ranges:

¹ 30,000 to < 40,000

² 40,000 to < 50,000

³ 50,000 to < 60,000

⁴ 60,000 to < 70,000

⁵ \$0 to < \$10 million

4.8 A Deed of Agreement between the sponsor and the Commonwealth was proposed and accepted during the negotiations for listing Oriprio. The submission did not request any changes to the subsidisation caps for Oriprio.

4.9 As a Category 4 submission, the financial estimates have not been independently evaluated.

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

5 PBAC Outcome

5.1 The PBAC recommended increasing the maximum quantity from 30 pessaries (2 packs) to 45 pessaries (3 packs) and reducing the number of repeats from 5 to 3 of the PBS listed progesterone 200 mg pessary (Oriprio) for the prevention of preterm birth, to align the number of patient co-payments with another brand of progesterone (Utrogestan).

5.2 The PBAC noted that the ex-manufacturer price of Oriprio remained unchanged.

5.3 The PBAC noted an estimated net cost to the PBS/RPBS of \$0 to < \$10 million over six years due to the loss of patient co-payments. The PBAC noted that the loss in average co-payments per patient (\$38.43) offsets the save from the reduction in DPMQ per patient (-\$13.27). This results in a net cost per patient of \$25.16 and hence the net cost to the PBS/RPBS of \$0 to < \$10 million over six years.

5.4 The PBAC noted that its recommendation was to align the number of co-payments

with Utrogestan and advised that, because Oriprio is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Utrogestan, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.

- 5.5 The PBAC noted that the submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

- 6.1 Amend maximum quantity and number of repeats as follows:

MEDICINAL PRODUCT, medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
PROGESTERONE progesterone 200 mg pessary, 15	12465C	3	45	3	Oriprio

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

Orion Laboratories welcomes the PBAC's decisions to increase the maximum quantity per script of Oriprio as this ensures equity for women at risk of preterm birth and provides a choice of medication to meet patient's personal needs.