

5.16 URSODEOXYCHOLIC ACID Tablet 500 mg, Ursofalk[®], Orphan Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested an Authority Required (STREAMLINED) listing for an additional strength of ursodeoxycholic acid for the treatment of primary biliary cirrhosis (PBC).

2 Requested listing

- 2.1 The submission requested the following new listing:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
URSODEOXYCHOLIC ACID tablet, 500 mg, 100	1	2	\$ [REDACTED]	Ursofalk [®]	Orphan Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Primary biliary cirrhosis
PBS Indication:	Primary biliary cirrhosis
Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

For more detail on PBAC's view, see section 6 "PBAC outcome"

3 Background

- 3.1 Ursodeoxycholic acid was TGA registered in March 1999 for the treatment of chronic cholestatic liver diseases. The 500 mg strength was registered on October 2016 for the same indication.

- 3.2 Ursodeoxycholic acid was recommended by the PBAC at the June 2000 meeting for the treatment of PBC, but the 500 mg strength has not been considered by the PBAC previously.

For more detail on PBAC’s view, see section 6 “PBAC outcome”

4 Current situation

- 4.1 The sponsor claimed that patients in a higher weight bracket are required to take multiple capsules of the currently listed strength. The minor submission claimed that the higher strength tablets would substitute for two of the 250 mg strength capsules and therefore reduce pill burden for some patients.

Sponsor hearing

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

Consumer comments

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

5 Estimated PBS usage & financial implications

- 5.1 The sponsor proposed an AEMP of \$ [REDACTED] (DPMQ = \$ [REDACTED]) for the 500 mg strength. This is lower than the PBS-listed price for ursodeoxycholic acid 250 mg capsules (AEMP = \$272.00 and DPMQ = \$306.96).
- 5.2 The minor submission estimated a net save to the PBS of less than \$10 million in Year 5 of listing, with a total net save to the PBS of less than \$10 million over the first 5 years of listing. The submission assumed that the number of prescriptions will not change, as one prescription for ursodeoxycholic acid 500 mg at a maximum quantity of one pack will substitute for one prescription of the 250 mg strength at the maximum quantity of two packs. The number of scripts and estimated financial impact to the PBS and RPBS is summarised in Table 1 below.

Table 1: Number of expected prescription numbers of ursodeoxycholic acid 500 mg

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of PBS scripts	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Number of RPBS scripts	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
PBS financial impact	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]
RPBS financial impact	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]
Total financial impact	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]

Source: Utilisation & Cost Model Spreadsheet, Minor Submission

The redacted table shows that at year 5, the estimated number of patients was 10,000 – 50,000.

For more detail on PBAC's view, see section 6 "PBAC outcome"

6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required (STREAMLINED) listing of ursodeoxycholic acid 500 mg tablets for the treatment of primary biliary cirrhosis.
- 6.2 The PBAC noted that the proposed maximum quantity and number of repeats provides an equivalent amount of ursodeoxycholic acid as the current PBS listed ursodeoxycholic acid 250 mg capsules.
- 6.3 The PBAC noted that the listing of the 500 mg strength would result in a cost saving to the PBS as the proposed AEMP of the 500 mg strength is lower than the price of the current listed 250 mg strength.
- 6.4 The PBAC noted that the listing of the 500 mg strength would reduce the pill burden for some patients.
- 6.5 The PBAC advised that consistent with the existing arrangements for the current listed 250 mg strength, ursodeoxycholic acid is suitable for prescribing by nurse practitioners within collaborative arrangements for continuing treatment only.
- 6.6 The PBAC advised that the Early Supply Rule should not apply as it does not apply to the current listed 250 mg strength.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
URSODEOXYCHOLIC ACID Tablet 500 mg, 100	1	2	Ursofalk®	Orphan Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Primary biliary cirrhosis
PBS Indication:	Primary biliary cirrhosis
Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners. Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

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.