

5.20 BALSALAZIDE, Capsule, 750 mg balsalazide sodium, 280, Colazide[®], Fresenius Kabi Australia Pty Limited.

1 Purpose of Application

- 1.1 The minor submission sought to list a new pack size of 280 capsules of balsalazide on the PBS.
- 1.2 As PBS listings are based on pharmaceutical items, rather than pack sizes, the PBAC was requested to provide advice on an increase in maximum quantity for balsalazide capsules to 280, which would allow the supply of the pack size requested.

2 Requested listing

- 2.1 The submission requested no changes to the restriction criteria for balsalazide.

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

3 Background

- 3.1 Balsalazide is TGA registered for treatment of mild-to-moderate active ulcerative colitis, and maintenance of remission, in patients who are intolerant to sulfasalazine.
- 3.2 Balsalazide was recommended by the PBAC on a cost-minimisation basis against mesalazine enteric coated tablets at the March 2005 PBAC meeting.

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

4 Basis for the request

- 4.1 The submission claimed that there is a need to increase the maximum quantity so that patients have sufficient capsules for the treatment of active disease.
- 4.2 The recommended dosage in the product information for treatment of active disease is three capsules three times a day, or 270 capsules per month. The recommended dosage for maintenance treatment is two capsules twice a day, or 120 capsules per month. The current maximum quantity for balsalazide is 180 capsules.
- 4.3 The submission claimed that this meant that when treating active disease either

doctors need to request an increase in the maximum quantity by telephone authority, or patients may need to fill their prescription more frequently and as a result attend their doctor more regularly for a new prescription.

- 4.4 The PBAC previously recommended listing of balsalazide on a cost-minimisation basis compared to mesalazine.

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

5 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Estimated PBS usage & financial implications

- 5.3 The minor submission requested the same price per capsule (AEMP) for balsalazide (750 mg, 280 capsules) as the current PBS-listed 180 capsule pack. A summary of the calculations to determine the price for the new pack size are presented below:

Table 1: Colazide price per capsule calculations

	AEMP	Price to Pharmacy (PTP)	DPMQ	Price per capsule (based on AEMP)
AEMP for 180-capsule pack	\$95.12	\$102.27	\$112.83	\$0.53
Proposed AEMP for 280-capsule pack	\$147.96	\$159.09	\$169.65	\$0.53

Source: Colazide Financial Implications Excel workbook, Pricing calculations worksheet, pg11 of the submission

- 5.4 The submission assumed that the uptake of balsalazide 280-capsule pack would replace the existing 180-capsule pack and did not expect it to impact on the overall market size for balsalazide.
- 5.5 The submission also anticipated a reduction in the number of prescriptions and number of Authority Required approvals, as patients would receive sufficient medicines for one months’ supply with the new maximum quantity.
- 5.6 The minor submission estimated a total net cost to the PBS of less than \$10 million over the first 5 years of listing (table 2), due to a reduction in the number of co-payments. The submission also claimed savings to the MBS as a result of a reduction in the number of consultations. The sponsor assumed that all patients will attend only 2 appointments, instead of 3 per year.

Table 2: Estimated net cost to the PBS/RPBS for balsalazide 280-capsule pack

	Year 1	Year 2	Year 3	Year 4	Year 5
Projected net cost of new listing to the PBS/RPBS less co-payments	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Projected net costs of displaced medicines to the PBS/RPBS less co-payments	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net impact to the PBS/RPBS to the PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net impact to the MBS	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]
Net impact to government	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]

Source: Financial Implications Workbook

5.7 However, there appeared to be some discrepancies in the estimated financial impact:

- The submission assumed that 80% of patients will be on active treatment or maintenance treatment at 8 capsules per day and will require larger quantities. This is inconsistent with the previous estimate that 17% of patients would be on active treatment, and the recommended dosage for maintenance treatment. Although the pre-PBAC response (p2) provided a sensitivity analysis where 17% of patients required an increase in maximum quantity, this was still higher than observed in the PBS data.
- The submission assumed that all of these patients are currently getting additional scripts to meet their dosing requirements, whilst also assuming that 80% of them are also seeking a telephone authority approval for an increased maximum quantity. These estimates have not been justified and appear to overestimate the reduction in co-payments and/or the reduction in the number of telephone authority requests. The pre-PBAC response (p2) acknowledged this and applied revised estimates which resulted in a small saving to government.
- The submission also assumed that all current patients require higher quantities, and all will attend additional appointments to get more scripts. This is inconsistent with the previous estimates that only 80% of patients require higher quantities, and that 80% of these are currently seeking a telephone authority for increased maximum quantities, and therefore overestimates the savings to Medicare.
- The expected saving from reduced visits to consultant physicians (MBS Item 116), will not be realised as the system is considered to act at capacity and a reduction in its use by one groups of patients does not result in a harvestable saving. The pre-PBAC response (p2) argued that regardless of whether the MBS is acting at capacity or not, the opportunity cost forgone by providing an additional consultation to a patient for the provision of a Colazide prescription presents a tangible and quantifiable cost to the healthcare

system.

- The increased risk of wastage was not addressed by the submission. The pre-PBAC response (p2) claimed that wastage would be consistent with other PBS listed medicines of a relapsing-remitting nature and would be offset by savings to the MBS. However, this was inadequately justified.

5.8 The PBAC therefore considered that the submission's assumptions and the resulting estimate of financial implications did not appear well justified.

5.9 The PBAC noted that there is an upcoming DUSC review to assess whether the increasing utilisation of 5-aminosalicylic acid medicines is due to more patients receiving treatment or higher doses (DUSC Outcome Statement, September 2016). The PBAC noted that there may be grounds to confirm the cost-effectiveness of colitis treatments used at higher doses.

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

6 PBAC Outcome

6.1 The PBAC deferred the request to increase the maximum quantity of the currently listed pharmaceutical item balsalazide (Colazide®) to 280 capsules, to allow further analysis of utilisation, and consideration of the impact that an increase in maximum quantity may have on wastage, as well as the impact of higher doses on quality use of medicines and the cost-effectiveness of balsalazide treatment.

6.2 The PBAC recalled that it recommended the listing of balsalazide on a cost-minimisation basis compared to mesalazine. The recommended maximum quantity was based on trial data and the dose of the comparator, mesalazine.

6.3 The PBAC noted that while the requested increase in maximum quantity would allow for the supply of one months' treatment of active disease, the recommended course of treatment for active disease is only 12 weeks; whereas each prescription provides for five repeats, or equivalent to six months treatment of active disease. As such, an increase in the maximum quantity increased the risk of wastage, and would also allow for use at higher doses than considered cost-effective at the time this listing was recommended.

6.4 The PBAC considered the submission's claim that 80% of patients require larger quantities of balsalazide was not adequately justified. The PBAC noted that PBS dispensing data for the 2016 calendar year indicated that 88% of PBS subsidised dispensing was for amounts less than or equal to 180 capsules. The PBAC therefore considered that further analyses are required to investigate the current prescribing pattern for balsalazide, to determine whether there is a need for a change to the

maximum quantity.

- 6.5 The PBAC also noted that the DUSC is undertaking further analyses to understand the patterns of use of 5-ASAs, including balsalazide, and considered that the findings would be relevant to this request.
- 6.6 The PBAC noted that this submission does not meet the criteria for an Independent Review because it relates to an existing listing.

Outcome:

Deferred

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.

November 2017 addendum to the July 2017 PBAC Minutes:

4.06 BALSALAZIDE

**Capsule, 750 mg balsalazide sodium, 280,
Colazide[®], Fresenius Kabi Australia Pty Limited**

At the July 2017 PBAC meeting, the Committee considered the request to increase the maximum quantity of the currently listed pharmaceutical item balsalazide (Colazide[®]) to 280 capsules. The PBAC previously considered the submission's claim that 80% of patients require larger quantities of balsalazide was not adequately justified.

The PBAC deferred the recommendation as it was noted that the Drug Utilisation Subcommittee (DUSC) was due to review the patterns of use of 5-aminosalic acids (5-ASAs), including balsalazide.

Following the availability of the September 2017 DUSC review on the utilisation of 5-ASAs (available on PBS website), the sponsor requested that the PBAC reconsider the submission to increase the maximum quantity of balsalazide to 280 capsules in the November 2017 PBAC meeting. The review on the utilisation of 5-ASAs, was considered by the PBAC at the November 2017 meeting.

The PBAC recommended an increase in the maximum quantity of balsalazide to 280 capsules. The listing of the 280 capsule pack size of balsalazide will be the same price per capsule (AEMP) as the existing 180 capsule pack size. The 180 capsule pack size will be delisted upon the listing of the 280 capsule pack size. Although the PBAC considered there may be potential for wastage, it considered that this would be minimal for this chronic condition.

Outcome

Recommended

9 Recommended listing

Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
BALSALAZIDE Capsule, 750 mg balsalazide sodium, 280	280	5	Colazide Fresenius Kabi Australia Pty Limited
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:	Ulcerative colitis		
PBS Indication:	Ulcerative colitis		
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required - Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined		
Clinical criteria:	Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR Patient must be intolerant to sulfasalazine		
Administrative Advice	Not for the treatment of Crohn disease Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing the medicine for, a patient has been initiated by a medicine be found in the Explanatory Notes for Nurse Practitioners.		

10 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.

11 Sponsor's Comment

The sponsor had no comment.