

6.11 FENTANYL CITRATE

Tablet (sublingual) 100 micrograms (as citrate), Tablet (sublingual) 200 micrograms (as citrate), Abstral®, A.Menarini Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested an increase in the maximum quantity per 10 pack of Abstral, fentanyl citrate sublingual tablets, 100 microgram and 200 microgram, for the initial treatment for dose titration of cancer patient with breakthrough pain (BTP) attributable to this condition.

2 Requested changes to the existing listing

- 2.1 The requested changes to the maximum quantity of the current listing are shown in italics and deletions are in strikethrough. No other changes to the current restriction were requested.

Name, Restriction, Manner of administration and form	Max qty packs	Max qty units	No. of repeats	Dispensed Price for Max Qty	Proprietary Name and Manufacturer
FENTANYL					A Menarini
100 microgram sublingual tablet, 10	42	40 20	0	\$159.74	Abstral® Australia Pty Ltd
200 microgram sublingual tablet, 10	4 2	40 20	0	\$159.74	

3 Background

- 3.1 Fentanyl citrate sublingual tablets (Abstral®) are TGA registered for the management of BTP in adults with cancer who are already receiving maintenance opioid therapy for chronic pain. BTP is a transient exacerbation of otherwise controlled chronic background pain.
- 3.2 Fentanyl citrate (Abstral®) has been listed on the Palliative Schedule of the PBS since February 2016 for the treatment of cancer patients with BTP.
- 3.3 All listed strengths, 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg and 800 mcg have flat pricing on the PBS. The current listing includes an initial treatment for dose titration (10 tablets, no repeats will be authorised) and continuation treatment

phase (60 tablets, up to 3 repeats).

- 3.4 The minor submission requested an increase in the maximum quantity to 2 packs of 10 tablets, for the initial treatment for dose titration, for both the 100 mcg and 200 mcg tablets. The submission claimed that this increase would allow patients to achieve the average effective dose of 400 mcg or up to the maximum tolerated dose of 800 mcg without having to re-visit the doctor or incur another co-payment.

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

4 Clinical place for the proposed therapy

- 4.1 Cancer patients may experience two types of pain: persistent background pain, for 12 or more hours per day; and transitory exacerbations of pain which "breaks through" the background medication, known as breakthrough pain (BTP).
- 4.2 The approved Product information for fentanyl citrate (Abstral®) indicates that the use of Abstral® must follow titration rules that are Abstral® specific.
- 4.3 The aim of dose titration is to identify an optimal maintenance dose for treatment of BTP episodes that provides adequate analgesia with an acceptable level of adverse reactions. The optimal dose of Abstral® is determined by upward titration, on an individual patient basis. The initial dose should be 100 mcg titrating upwards as necessary. The minor submission indicated that the current maximum quantity for the dose titration packs does not allow some patients to reach their optimal maintenance dose within one script.
- 4.4 Abstral® is not a generic form of any other fentanyl product and it is not equivalent on a µg per µg (1:1) basis with any other fentanyl product. Due to differences in the pharmacokinetic properties of different fentanyl products and the individual variability of patients, patients switching from other fentanyl containing products to Abstral® must also start with the 100 mcg dose and follow Abstral® specific titration process contained in the approved Product information sheet.

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 and welcomed the input from health care professionals (1) via the Consumer Comments facility on the PBS website. The comments described difficulty for these patients to see a doctor easily and indicated that the proposed increase in the maximum quantity would aid in the correct treatment of these terminally ill patients with fentanyl.

Estimated PBS usage & financial implications

- 5.3 The submission did not request any changes to the current prices for Abstral® in the PBS. With an increase in the maximum quantity to 2 x 10 initiation packs, the revised Dispensed Price Maximum Quantity (DPMQ) prices for changes would be:
- Abstral® fentanyl 100 mcg sublingual tables, 2 x 10s, DPMQ of \$ 159.74
 - Abstral® fentanyl 200 mcg sublingual tables, 2 x 10s, DPMQ of \$ 159.74
- 5.4 The submission stated that the proposed change to the listing was not expected to increase the gross amount of Abstral® dispensed to patients and would likely result in some savings to the MBS budget through reduced consultations for a new script.
- 5.5 The submission presented the estimated costs to the PBS/RPBS associated with the listing of Abstral®. As an increase in the maximum quantity per script would result in a reduction of the net prescriptions, there was an overall net cost to the PBS/RPBS across the forward projections resulting from the reduced co-payments from patients.
- 5.6 The submission also presented the proposed net implications for the health budget. Due to the predicted reduction in MBS costs, the proposed amendment to the listing of Abstral was predicted by the sponsor to be a cost saving in each of the forward projected years.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the changes to the current Authority Required listing of fentanyl citrate (Abstral®) on the Palliative Care Schedule of the PBS by increasing the maximum quantity of the 100 mcg and 200 mcg presentations from 10 to 20 tablets per prescription for dose titration in the initiation of treatment of cancer patients with breakthrough pain.

- 6.2 The PBAC advised that the recommended changes to the listing would not be expected to increase the gross amount dispensed to patients however, it would incur additional costs to the PBS.
- 6.3 The PBAC considered that the reduction in MBS items as proposed by the sponsor were unlikely to be realised in actuality and that the recommended changes in the maximum quantity of fentanyl 100 mcg and 200 mcg presentations would result in a cost to the PBS and the Government health budgets.
- 6.4 The PBAC additionally recommended future discussion in regards to the growing size of dose titration packs and the potential issue that this might represent in terms of the quality use of these medicines, particularly in terms of product diversion. The PBAC noted that the submission did not fully address quality use of medicines issues and considered that all future submissions of drugs of high risk of dependence must fully address these issues. However, the PBAC considered that, in the case of this particular population (cancer patients undergoing Palliative Care), this risk is considered to be low.

7 Recommended listing

- 6.5 Amend maximum quantity as follows:

Name, Restriction, Manner of administration and form	Max qty packs	Max qty units	No. of repeats	Proprietary Name and Manufacturer	
FENTANYL					
100 microgram sublingual tablet, 10	2	20	0	Abstral®	A Menarini Australia Pty Ltd
200 microgram sublingual tablet, 10	2	20	0		

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.