

12.03 Ondansetron Correspondence from Medical Oncology Group of Australia (MOGA)

1 Purpose

- 1.1 To amend the PBS listings for ondansetron tablets and wafers, to enable patients being treated with oral chemotherapy to be prescribed a maximum quantity of 10 with 1 repeat, in line with current PBS listings of ondansetron for nausea and vomiting associated with radiotherapy.

2 Requested listing

- 2.1 The Secretariat has suggested that the existing restriction for ondansetron for nausea and vomiting associated with radiotherapy be amended as follows:

Name, Restriction, Manner of administration and form	PBS Code	Max. Qty	№.of Rpts	DPMQ	Proprietary Manufacturer	Name and
ONDANSETRON						
Ondansetron 4 mg wafer, 10	8412R	10	1	\$23.10	Various	Various
Ondansetron 8 mg wafer, 10	8413T	10	1	\$28.32		
Ondansetron 4 mg tablet, 10	1594X	10	1	\$20.65		
Ondansetron 8 mg tablet, 10	1595Y	10	1	\$25.87		
Ondansetron 4 mg orally disintegrating tablet, 10	5472B	10	1	\$20.65		
Ondansetron 8 mg orally disintegrating tablet, 10	5473C	10	1	\$25.87		

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
Restriction Level / Method: <input checked="" type="checkbox"/> Authority Required - Streamlined
PBS Indication: Nausea and vomiting
Clinical criteria:
The condition must be associated with radiotherapy being used to treat malignancy; OR
The condition must be associated with oral chemotherapy being used to treat malignancy

3 Background and current situation

Current situation

- 3.1 On 23 August 2019, the Medical Oncology Group of Australia (MOGA) wrote to the PBAC requesting changes to ondansetron listings with indications for nausea and vomiting associated with cytotoxic chemotherapy used to treat malignancy to allow a maximum quantity of 10 plus one repeat to match the radiotherapy indication.

3.2 In justifying this request MOGA stated that:

- the expected additional use would be predominantly in patients receiving temozolomide (without radiotherapy) and other oral chemotherapeutics which cause nausea for which other antiemetic's have not been successful;
- it did not expect patients receiving intravenous chemotherapeutics would require 'extended' ondansetron as they have access to palonosetron +/- netupitant; and
- the price of ondansetron had reduced significantly since the introduction of generic brands.

4 PBAC Outcome

4.1 The PBAC recommended extending the existing General Schedule listings for ondansetron tablets, orally disintegrating tablets and wafers for the treatment of nausea and vomiting associated with radiotherapy, to include treatment of nausea and vomiting associated with oral chemotherapy being used to treat malignancy.

4.2 The PBAC noted the significant price reductions of ondansetron tablets, oral disintegrating tablets and wafers since first listing, and considered that at the current prices, the expanded use of ondansetron to include these patients would be cost-effective.

4.3 The PBAC considered that patients receiving oral chemotherapy who required more than the currently available maximum quantity of 4 units were likely to already be prescribed this through requests for an increased maximum quantity, and therefore considered that the proposed changes were unlikely to increase utilisation or have a financial impact to the PBS.

4.4 The PBAC advised that the changes should also apply to granisetron 2 mg tablets which are currently PBS listed for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Outcome

Recommended

5 Recommended Listing

5.1 Amend the following existing listings to read as follows:

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Name, Restriction, Manner of administration and form	PBS Code	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
ONDANSETRON Ondansetron 4 mg wafer, 10 Ondansetron 8 mg wafer, 10 Ondansetron 4 mg tablet, 10 Ondansetron 8 mg tablet, 10 Ondansetron 4 mg orally disintegrating tablet, 10 Ondansetron 8 mg orally disintegrating tablet, 10	8412R 8413T 1594X 1595Y 5472B 5473C	10 10 10 10 10 10	1 1 1 1 1 1	Various	Various
GRANISETRON Granisetron 2 mg tablet, 5	8873B	5	1	Kytril	Clinect 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
Restriction Level / Method: <input checked="" type="checkbox"/> Authority Required - Streamlined
PBS Indication: Nausea and vomiting
Clinical criteria:
The condition must be associated with radiotherapy being used to treat malignancy; OR
The condition must be associated with oral chemotherapy being used to treat malignancy
Administrative Advice: (applies to ondansetron 4 mg wafers & orally disintegrating tablet) Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron 4 mg wafer are equivalent for the purposes of substitution.
Administrative Advice: (applies to ondansetron 8mg wafers & orally disintegrating tablet) Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron 8 mg wafer are equivalent for the purposes of substitution.

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

6 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.

7 Sponsor's Comment

The sponsor had no comment.