CONSULTATION

PHARMAC
Pharmaceutical Management Agency

7 August 2014

Zoledronic Acid (Zometa)

PHARMAC is proposing to amend the listing of zoledronic acid 0.8 mg per ml, 5 ml (Zometa) on the Pharmaceutical Schedule to include Hospital and Community funding for treatment of hypercalcaemia of malignancy, treatment of pain in patients with bone metastases and prevention of skeletal related events (SRE) in patients with bone metastases

Details of the proposal

Zoledronic acid (Zometa)

- Zoledronic acid (Zometa) would be listed in Section B of the Pharmaceutical Schedule from 1 February 2015 at the following subsidy (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Strength	Pack size	Price and Subsidy
Zoledronic acid	Inj	Zometa	0.8 mg per ml, 5 ml	1	$550.00

We note that zoledronic acid (Zometa) is already currently listed in Part II of Section H at the price above.

- A confidential rebate would apply to Zometa which would reduce its net price.
- Zometa would have subsidy and delisting protection until 31 January 2018.
- Zoledronic acid (Zometa) would be listed subject to the following restrictions in Section B and Part II of Section H of the Pharmaceutical Schedule:

Section B

Special Authority for Subsidy
Initial application only from an oncologist or palliative care specialist. Approvals valid without further renewal for applications meeting the following criteria:
Either:
1. Patient has hypercalcaemia of malignancy; or
2. Both
   - 2.1. Patient has bone metastases; and
   - 2.2. Either
     - 2.2.1. Patient has severe bone pain resistant to standard first-line treatments; or
     - 2.2.2. Patient is at risk of skeletal-related events (pathological fracture, spinal cord compression, radiation to bone or surgery to bone)

Part II of Section H

Restricted
Oncologist or palliative care specialist
Either:
1. Patient has hypercalcaemia of malignancy; or
2. Both

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2.1. Patient has bone metastases; and
2.2. Either
    2.2.1. Patient has severe bone pain resistant to standard first-line treatments; or
    2.2.2. Patient is at risk of skeletal-related events (pathological fracture, spinal cord compression, radiation to bone or surgery to bone)

About zoledronic acid

Zoledronic acid 4 mg in 5 ml (Zometa) is a bisphosphonate indicated for the prevention of skeletal-related events (in patients with advanced malignancies involving bone, and for the treatment of tumour-induced hypercalcaemia. Zoledronic acid 4 mg in 5 ml is currently listed on the Hospital Medicines List (HML) restricted to treatment of hypercalcaemia of malignancy, but is not listed in Section B of the Pharmaceutical Schedule.

PHARMAC has received requests for widening of funded funded access to zoledronic acid (4 mg in 5 ml) for the treatment of hypercalcaemia of malignancy and for the prevention of pain and skeletal-related events (SREs) in patients with bone metastases (including in the absence of hypercalcaemia) both in the hospital and in the primary care setting (hospices and general community). Pamidronate is an alternative bisphosphonate funded without restriction in hospitals and the community; however, it requires a 90 minute infusion which may not be practical in some settings. Bisphosphonate treatment is mainly used in palliative care, however, many hospices cannot access DHB-funded zoledronic acid, even where dispensing into the community is permitted by the HML rules, because this requires a DHB hospital doctor to write the prescription which is not an option or not practical in many instances. For this reason, a Section B listing is being proposed to ensure consistency of access by hospices.

PTAC and its Analgesic Subcommittee have reviewed the funding of zoledronic acid. At its November 2013 meeting PTAC recommended that zoledronic acid (4 mg in 5 ml) should be funded in hospital and in the Community subject to Special Authority criteria for the treatment of hypercalcaemia of malignancy, treatment of pain in patients with bone metastases and prevention of skeletal-related events (SRE) in patients with bone metastases if cost neutral to pamidronate taking into account the costs of infusion services and compounding. The Committee considered that the shorter infusion time of zoledronic acid (15 minutes) compared with pamidronate (90 minutes) may be beneficial and more convenient for patients

The minutes for the relevant reviews can be found on the PHARMAC website through the following links:

- http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=869