

7 August 2014

Tobramycin solution for inhalation (Tobi)

PHARMAC is proposing to list tobramycin solution for inhalation (Tobi) on the Pharmaceutical Schedule for patients with cystic fibrosis.

- Tobramycin (Tobi) would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 November 2014 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Strength	Pack size	Price and subsidy
Tobramycin	Solution for inhalation	Tobi	60 mg per ml, 5ml	56	\$2,200.00

- A confidential rebate would apply to Tobi which would reduce the net price of the treatment.
- Tobi would have subsidy and delisting protection until 31 October 2017.
- Tobramycin solution for inhalation would be listed subject to the following restrictions in Section B and Part II of Section H of the Pharmaceutical Schedule:

Section B

Subsidy by endorsement

Subsidised only if prescribed for a cystic fibrosis patient and the prescription is endorsed accordingly.

Part II of Section H

Restricted

Patient has cystic fibrosis.

About tobramycin

Tobramycin is an aminoglycoside antibiotic produced by *Streptomyces tenebrarius*. It acts primarily by disrupting protein synthesis, leading to altered cell membrane permeability, progressive disruption of the cell envelope, and eventual cell death.

Tobi is a tobramycin solution for inhalation indicated for the management of cystic fibrosis patients with *P. aeruginosa* infection. Each single-use 5 mL ampule contains 300 mg tobramycin and 11.25 mg sodium chloride in sterile water for injection.

Currently IV tobramycin is listed on the Pharmaceutical Schedule for patients meeting the following criteria:

Subsidised only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly

IV tobramycin is not indicated for nebulisation so clinicians are currently prescribing this product for nebulization under Section 25 of the Medicines Act 1984.

The Respiratory Subcommittee reviewed Tobi at its 30 April 2014 meeting. The minutes from this meeting have not been reviewed by PTAC and are not published yet, but the Application Tracker for tobramycin will be updated as soon as the minutes are available. PHARMAC have also sought advice from Cystic Fibrosis specialists who gave advice about the appropriate therapeutic levels of tobramycin to treat this indication. This proposal aligns with their advice.