CONSULTATION

PHARMAC
Pharmaceutical Management Agency

7 August 2014

Omalizumab (Xolair)

PHARMAC is proposing to list omalizumab (Xolair) on the Pharmaceutical Schedule for patients with severe persistent allergic asthma.

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

Chemical	Presentation	Brand	Strength	Pack size	Price and subsidy
Omalizumab	Injection	Xolair	150mg	1	$500.00

- A confidential rebate would apply to Xolair which would reduce the net price of the treatment.

- Xolair would have subsidy and delisting protection until 31 October 2017.

- Omalizumab 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 a respiratory physician. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Patient is over the age of 6; and
2. Patient has a diagnosis of severe, life threatening asthma; and
3. Past or current evidence of atopy, documented by skin prick testing or RAST; and
4. Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
5. Proven compliance with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated; and
6. Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; and
7. At least four admissions to hospital for a severe asthma exacerbation over the previous 24 months with at least one of those being in the previous 12 months; and
8. An Asthma Control Questionnaire (ACQ-5) score of at least 3.0 as assessed in the previous month

Renewal only from a respiratory physician. Approvals valid for 2 years for applications meeting the following criteria:
Both

1. A reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 1.0 from baseline; and
2. A reduction in the maintenance oral corticosteroid dose of at least 50% from baseline.

Part II of Section H

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Initiation
Respiratory physician
Re-assessment required after 6 months
All of the following:

1. Patient is over the age of 6; and
2. Patient has a diagnosis of severe, life threatening asthma; and
3. Past or current evidence of atopy, documented by skin prick testing or RAST; and
4. Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
5. Proven compliance with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated; and
6. Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; and
7. At least four admissions to hospital for a severe asthma exacerbation over the previous 24 months with at least one of those being in the previous 12 months; and
8. An Asthma Control Questionnaire (ACQ-5) score of at least 3.0 as assessed in the previous month

Continuation
Respiratory physician
Re-assessment required after 6 months
Both:

1. A reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 1.0 from baseline; and
2. A reduction in the maintenance oral corticosteroid dose of at least 50% from baseline.

About omalizumab

Omalizumab is a humanised monoclonal antibody indicated for the reduction of asthma exacerbations and control of asthma symptoms when given as add on therapy for patients with severe persistent allergic asthma who have an IgE level ≥ 30 IU/mL and a positive test to a perennial aeroallergen that is uncontrolled by current treatments.

Omalizumab is administered by a subcutaneous injection.

PTAC and its Respiratory Subcommittee have reviewed omalizumab on a number of occasions most recently at their meetings on the 8th November 2013 and 24th May 2013 respectively. The recommendation has been that omalizumab be listed on the Pharmaceutical Schedule with a medium priority. PTAC recommended that PHARMAC develop Special Authority criteria with strict entry and exit criteria and the facility for a trial of treatment.

The criteria proposed for omalizumab in this consultation are those recommend by the Respiratory Subcommittee in April 2014 at its meeting in April 2014. The minutes of this meeting have not yet been reviewed by PTAC; they will be reviewed at its August meeting, The Application Tracker for omalizumab will be updated as soon as possible after PTAC's meeting.

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

- http://www.pharmac.health.nz/assets/ptac-respiratory-subcommittee-minutes-2013-05-24.pdf
- http://www.pharmac.health.nz/assets/ptac-minutes-2013-11.pdf