CONSULTATION

PHARMAC
Pharmaceutical Management Agency

7 August 2014

Glycopyrronium (Seebri Breezhaler), indacaterol (Onbrez Breezhaler) and indacaterol with glycopyrronium (Ultibro Breezhaler)

PHARMAC is proposing to list the following chronic obstructive pulmonary disease (COPD) treatments on the Pharmaceutical Schedule:

- Glycopyrronium (Seebri Breezhaler);
- Indacaterol (Onbrez Breezhaler); and
- a possible future listing of indacaterol with glycopyrronium (Ultibro Breezhaler) for patients with COPD - subject to Medsafe approval, recommendation to fund from PHARMAC's clinical advisors, consultation and PHARMAC approval.

We are also proposing to make a new sub-heading in the Respiratory and Allergies therapeutic group which would include tiotropium (Spiriva) and glycopyrronium.

Details of the proposal

- Glycopyrronium (Seebri Breezhaler) and indacaterol (Onbrez Breezhaler) 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; ex GST):

Chemical	Presentation	Brand	Strength	Pack size	Price and subsidy
Glycopyrronium	Powder for inhalation	Seebri Breezhaler	50 mcg	30 dose OP	$61.00
Indacaterol	Powder for inhalation	Onbrez Breezhaler	150 mcg	30 dose OP	$61.00
Indacaterol	Powder for inhalation	Onbrez Breezhaler	300 mcg	30 dose OP	$61.00

- Confidential rebates would apply to Seebri Breezhaler and Onbrez Breezhaler which would reduce the net prices of the treatments.
- Seebri Breezhaler and Onbrez Breezhaler would have subsidy and delisting protection until 31 October 2017.
- A new heading 'Long-Acting Muscarinic Antagonists' would be added under the current subgroup 'Inhaled Anticholinergic Agents' in the Respiratory System and Allergies therapeutic group in Section B, and Part II of Section H, of the Pharmaceutical Schedule.
- Seebri Breezhaler and Spiriva would be listed under the Long-Acting Muscarinic Antagonists heading and would be listed subject to the following restrictions (which are the current restriction applying to Spiriva) which would sit at the Long-Acting Muscarinic Antagonists heading level in Section B and Part II of Section H of the

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Pharmaceutical Schedule (i.e. the restrictions would apply to both Seebri Breezhaler and Spiriva):

Section B

Special Authority for Subsidy
Initial application from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

1 To be used for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD; and
2 In addition to standard treatment, the patient has trialled a short acting bronchodilator dose of at least 40 µg ipratropium q.i.d for one month; and
3 Either:
The patient's breathlessness according to the Medical Research Council (UK) dyspnoea scale is:
3.1 Grade 4 (stops for breath after walking about 100 meters or after a few minutes on the level); or
3.2 Grade 5 (too breathless to leave the house, or breathless when dressing or undressing); and

Applicant must state recent measurement of:

4 All of the following:
4.1 Actual FEV_1 (litres); and
4.2 Predicted FEV_1 (litres); and
4.3 Actual FEV_1 as a % of predicted (must be below 60%); and
5 Either:
5.1 Patient is not a smoker (for reporting purposes only); or
5.2 Patient is a smoker and has been offered smoking cessation counselling; and
6 The patient has been offered annual influenza immunization;

Renewal only from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

1 Patient is compliant with the medication; and
2 Patient has experienced improved COPD symptom control (prescriber determined); and

Applicant must state recent measurement of:

3 All of the following:
3.1 Actual FEV_1 (litres); and
3.2 Predicted FEV_1 (litres); and
3.3 Actual FEV_1 as a % of predicted.

Part II of Section H

Initiation
All of the following:

1 To be used for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD; and
2 In addition to standard treatment, the patient has trialled a short acting bronchodilator dose of at least 40 µg ipratropium q.i.d for one month; and
3 Either:
The patient's breathlessness according to the Medical Research Council (UK) dyspnoea scale is:
3.1 Grade 4 (stops for breath after walking about 100 meters or after a few minutes on the level); or
3.2 Grade 5 (too breathless to leave the house, or breathless when dressing or undressing); and

4 Actual FEV_1 as a % of predicted, must be below 60%
5 Either:
5.1 Patient is not a smoker (for reporting purposes only); or
5.2 Patient is a smoker and has been offered smoking cessation counselling; and
6 The patient has been offered annual influenza immunization; and

- The following note would be added to the listing of Spiriva (tiotropium bromide, powder for inhalation, 18 mcg per dose) in Section B of the Pharmaceutical Schedule.

  > Note: tiotropium treatment will not be subsidised if patient is also receiving treatment with subsidised glycopyrronium

- The following note would be added to the listing of Spiriva (tiotropium bromide, powder for inhalation, 18 mcg per dose) in Part II of Section H of the Pharmaceutical Schedule.

  > Note: tiotropium treatment must not be used if the patient is also receiving treatment with subsidised glycopyrronium

- The following note would be added to the listing of Seebri Breezhaler in Section B of the Pharmaceutical Schedule:

  > Note: glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium

- The following note would be added to the listing of Seebri Breezhaler in Part II of Section H of the Pharmaceutical Schedule:

  > Note: glycopyrronium treatment must not be used if the patient is also receiving treatment with subsidised tiotropium

- Indacaterol with glycopyrronium (Ultibro Breezhaler) would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule provided it becomes Medsafe registered and it receives a positive funding recommendation from PTAC. We would likely consult again prior to listing Ultibro Breezhaler on the Pharmaceutical Schedule, particularly with respect to any Special Authority criteria that may apply or be amended. If listed, Ultibro Breezhaler would be listed at a price (ex GST) and subsidy of $110.00 per 30 capsules containing indacaterol 100 mcg with glycopyrronium 50 mcg powder for inhalation. A confidential rebate would apply to Ultibro Breezhaler which would reduce its net price.

- Access to Spiriva remains the same under this proposal and the proposal would have no effect on the Special Authority numbers currently applying to Spiriva patients.

About indacaterol and glycopyrronium

Indacaterol is a long acting inhaled beta-adrenoceptor agonist registered for long term, once-daily, maintenance bronchodilator treatment of airflow limitation in patients with chronic obstructive pulmonary disease (FEV_1 ≥30% to ≤80% of predicted values).

PTAC discussed indacaterol at its February 2012 meeting and recommended that indacaterol be listed on the Pharmaceutical Schedule only at a price that is cost neutral to a long acting beta-adrenoceptor agonist (LABA).

Glycopyrronium is a once a day inhalation Long-Acting Muscarinic Antagonist (LAMA) registered as a once-daily maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease.

PTAC discussed glycopyrronium at its February 2014 meeting and recommended glycopyrronium be listed on the Pharmaceutical Schedule under the same Special Authority criteria as tiotropium and only if it is cost-neutral to tiotropium.

Under this proposal, the Special Authority criteria for glycopyrronium is the same as that applying to tiotropium and would allow for patients to switch between the two products without re-applying under the initial criteria but does not allow for patients to be co-prescribed the two products.

The indacaterol/glycopyrronium combination product (Ultibro Breezhaler) would only be listed on the Pharmaceutical Schedule following Medsafe registration and a positive recommendation from PTAC (low, medium or high) and under any Special Authority criteria recommended by PTAC.

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

- http://www.pharmac.health.nz/assets/ptac-minutes-2012-02.pdf
- http://www.pharmac.health.nz/assets/ptac-minutes-2014-02.pdf