CONSULTATION

PHARMAC
Pharmaceutical Management Agency

18 December 2015

Proposal to list new Respiratory products and changes to some currently listed products.

PHARMAC is seeking feedback on a proposal to relating to a number of respiratory treatments for Chronic Obstructive Pulmonary Disease (COPD) and a spacer device. The proposal is a result of provisional agreements between PHARMAC and GlaxoSmithKline NZ Limited (GSK), PHARMAC and Boehringer Ingleheim and a 2014 agreement between PHARMAC and Novartis.

In summary, from 1 March 2016, this proposal would result in:

- Two new long-acting muscarinic antagonists (LAMAs) being funded;
- One of the LAMAs, Incruse Ellipta (umeclidinium), supplied by GlaxoSmithKline, being funded without a Special Authority (an endorsement that the patient had been diagnosed with COPD by spirometry would apply);
- Three new combination long-acting muscarinic antagonists/long-acting beta-adrenoceptor agonists (LAMA/LABAs) being funded subject to restrictions;
- One new inhaled cortical steroid (ICS)/LABA being funded;
- Changes to the LAMA Special Authority renewal criteria;
- Price and subsidy reductions for certain currently listed ICS/LABA and LABA products;
- Confidential rebates applying to all products except the Volumatic spacer; and
- The price of Volumatic being reduced.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 8th January 2016** to:

Christine Chapman
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: COPDconsultation@pharmac.govt.nz

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

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

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

Details of the proposal

From 1 March 2016, the price and subsidies for the following products in Section B and Part II of Section H of the Pharmaceutical Schedule would be as follows (prices are ex-manufacturer, exclusive of GST):

Therapeutic Class	Chemical	Presentation	Brand	Pack size	Price and subsidy	Supplier
LAMA	Tiotropium bromide	Powder for inhalation 18 mcg per dose	Spiriva	30 dose	$70.00*	Boehringer Ingelheim
LAMA	Tiotropium bromide	Solution for inhalation 2.5 mcg per dose	Spiriva Respimat	60 dose OP	$70.00	Boehringer Ingelheim
LAMA/LABA	Tiotropium bromide with olodaterol	Solution for inhalation 2.5 mcg with olodaterol 2.5 mcg	Spiolto Respimat	60 dose OP	$81.00	Boehringer Ingelheim
LAMA	Umeclidinium	Powder for inhalation 62.5 mcg	Incruse Ellipta	30 dose OP	$61.50	GSK
LAMA/LABA	Umeclidinium with vilanterol	Powder for inhalation 62.5 mcg with vilanterol 25 mcg	Anoro Ellipta	30 dose OP	$77.00	GSK
ICS/LABA	Fluticasone furoate with vilanterol	Powder for inhalation 100 mcg with vilanterol 25 mcg	Breo Ellipta	30 dose OP	$44.08	GSK
Spacer	Spacer device	800 ml	Volumatic	1	$6.50**	GSK
LAMA/LABA	Indacaterol with glycopyrronium	Powder for inhalation 110 mcg with glycopyrronium 50 mcg	Ultibro Breezhaler	30 dose OP	$110.00	Novartis

* Currently funded, there would be no change to price or subsidy

** Currently funded, price and subsidy would decrease from 1 March 2016.

- Confidential rebates would apply to all the above products , reducing their net price. except the Volumatic spacer

- Subsidy and delisting protection would apply until 1 March 2019 for the Boehringer Ingleheim products (tiotropium bromide and tiotropium bromide with olodaterol) and until 1 July 2019 for the GlaxoSmithKline products (umeclidinium, umeclidinium with vilanterol and fluticasone furoate with vilanterol).

LAMAs

- Umeclidinium (Incruse Ellipta) would be listed without a Special Authority or HML restriction and would be able to be prescribed by Nurse Practitioners with Respiratory scope. All umeclidinium prescriptions would require endorsement that the patient has been diagnosed as having COPD using spirometry to access subsidy. A note restricting subsidy to patients who are not receiving treatment with another LAMA would also apply to umeclidinium.

- Both tiotropium bromide presentations (the currently supplied Handihaler and the new Respimat) and the currently listed glycopyrronium inhaler would be funded under the following Special Authority criteria (deletions in strike out, additions in bold):

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:
Both ~~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.~~

- The LAMA Special Authority would remain interchangeable between tiotropium bromide and glycopyrronium.

- HML restrictions would remain unchanged for tiotropium bromide presentations (the currently supplied Handihaler and the new Respimat) and the currently listed glycopyrronium inhaler.

- The note restricting subsidy to patients who are not receiving treatment with another LAMA would also continue to apply.

LAMA/LABAs

- The LAMA/LABA combination products tiotropium bromide with olodaterol, umeclidinium with vilanterol and indacaterol with glycopyronnium would be listed under the following restrictions (Special Authority in the community and HML restriction in DHB hospitals):

> Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
> Both:
> 1 Patient has been stabilised on a long acting muscarinic antagonist; and
> 2 The prescriber considers that the patient would receive additional benefit from switching to a combination product.
>
> Renewal only from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
> Both:
> 1 Patient is compliant with the medication; and
> 2 Patient has experienced improved COPD symptom control (prescriber determined).
>
> Note: Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist

ICS/LABA

- Fluticasone furoate with vilanterol (Breo Ellipta) would be listed with no restrictions.

Currently listed ICS/LABA and LABA products

Under the proposed agreement with GSK, the prices of Seretide, Seretide Accuhaler, Serevent and Serevent Accuhaler would reduce effective from 1 March 2016 as follows (prices are ex-manufacturer, exclusive of GST):

Presentation of Pharmaceutical	*Current Price and subsidy*	*Price and subsidy from 1 March 2016*
Fluticasone 50 mcg with salmeterol 25 mcg (Seretide)	$37.48	$33.74
Fluticasone 125 mcg with salmeterol 25 mcg (Seretide)	$49.69	$44.08

Fluticasone 100 mcg with salmeterol 50 mcg (Seretide Accuhaler)	$37.48	$33.74
Fluticasone 100 mcg with salmeterol 50 mcg (Seretide Accuhaler)	$49.69	$44.08
Salmeterol 25 mcg (Serevent)	$26.46	$25.00
Salmeterol 50 mcg (Serevent)	$26.46	$25.00

Confidential rebates would continue to apply to Seretide and Seretide Accuhaler.

Background

Currently ~ 22,000 patients receive treatment with tiotropium bromide each year with approximately 4,000 patients new to treatment each year. Two LAMAs are currently listed under Special Authority criteria on the Pharmaceutical Schedule – tiotropium bromide which has been listed since February 2005 and glycopyrronium since November 2014.

In late 2014 and through 2015, PHARMAC received a number of applications for the funding of new respiratory products and in particular products for the treatment of COPD.

All of these products have been reviewed by either PTAC and/or the Respiratory Subcommittee. At its meeting on 2nd September 2015, the Respiratory Subcommittee reviewed all applications. The Subcommittee considered that each of these new products had undergone an extensive clinical trial programme and the clinical trials were of high quality. The Subcommittee considered the evidence showed no clinically meaningful superiority of the new products over existing listings and that there was a modest benefit in combination treatment versus single inhaler medication.

The Subcommittee considered none of the new products or the currently listed treatments is clearly superior within a class and no combination inhaler is clearly superior to concomitant mono-component therapy. The Subcommittee considered the main differences between treatments were in the dosing frequency and the delivery devices.

The Subcommittee recommended listing the new LAMA monotherapies without a Special Authority provided they were cost neutral to indacaterol or listing them subject to the current Special Authority criteria if they were cost neutral to glycopyrronium. It also recommended listing the LAMA/LABA combinations provided they were cost neutral to the Combined Pharmaceutical Budget and listing the 100 mcg fluticasone furoate with 25 mcg vilanterol if it were cost neutral to the equivalent fluticasone with salmeterol inhaler with a low priority.

These proposals would result in the listing of new pharmaceuticals and the amendments to the Pharmaceutical Schedule listing of current products which would improve patient access and treatment choices and result in savings to the combined pharmaceutical budget (CPB).

Long-acting Muscarinic Antagonists (LAMAs)

The Global Initiative for COPD states "Spirometry is required to make a clinical diagnosis of COPD; the presence of a postbronchodilator FEV_1/FVC <0.70 (i.e. an FEV_1 of 70% of predicted confirms the presence of airflow limitation and thus of COPD."

The Respiratory Subcommittee considers that there are some patients (estimated to be ~1,200) who have preserved lung function but exhibit other COPD symptoms such as exacerbations or CAT scores ≥ 10 or mMRC scores ≥ 2 who are not able to access treatment under the current Special Authority criteria. Under this proposal those patients would have access to umeclidinium.

The requirement to record the FEV_1 readings in the renewal application has been removed on the advice of the Respiratory Subcommittee as they considered FEV_1 does not indicate clinical responsiveness to these pharmaceuticals (meeting March 2015).

Long-acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists (LAMA/LABAs)

There are no combination LAMA/LABA products currently listed on the Pharmaceutical Schedule. These products would be listed under a Special Authority for the treatment for patients who have been stabilised on a LAMA and where the prescriber considers the patient would benefit from having a combination product.

The listing of glycopyrronium with indacaterol (Ultibro) was previously consulted on as part of the Novartis Agreement on the 7th of August 2014. At that time the listing of Ultibro was subject to Medsafe approval which has since been received.

Inhaled corticosteroid with Long-Acting Beta-Adrenoceptor Agonist (ICS/LABA)

Fluticasone furoate with vilanterol is a once daily ICS/LABA combination product. The Subcommittee noted that the product was more potent than fluticasone propionate with salmeterol, showed non-inferiority to fluticasone propionate with salmeterol in terms of lung function and a modest superiority in terms of quality of life in an indirect comparison.

The Subcommittee noted that the clinical trials showed non-inferiority to fluticasone propionate with salmeterol in terms of lung function and a modest superiority in terms of quality of life in an indirect comparison.

The clinical trials showed fluticasone furoate with vilanterol reduced exacerbations by 27% in COPD patients (not on LAMAs) compared to baseline or vilanterol monotherapy. The Subcommittee noted that fluticasone furoate plus vilanterol trials had a 3% rate of pneumonia requiring hospitalisation, and a correlation between the strength of the dose of fluticasone furoate and increased rates of pneumonia. The Subcommittee noted that there may be an increased risk of death from pneumonia with increasing strength of fluticasone furoate.

The Subcommittee recommended listing the 100 mcg fluticasone furoate with 25 mcg vilanterol cost neutral to the equivalent cost of fluticasone with salmeterol with a low priority and recommended declining listing of the high strength 200 mcg fluticasone furoate with 25 mcg vilanterol.