

21 October 2011

Approval of proposal on subsidy changes for some respiratory inhalation products and access restrictions to combination inhalers

The following proposals have been approved:

- Removal of the requirement for patients to be on separate ICS and LABA inhalers for at least three months prior to being eligible for funded combination inhalers.
- Fully funding fluticasone powder for inhalation (Flixotide Accuhaler).
- Reduction in the subsidies (through parity pricing) payable for:
 - a. budesonide with eformoterol ICS and LABA combination inhalers (Symbicort Turbuhaler and Vannair) to the net level of subsidy for the individual fluticasone (Flixotide) and salmeterol (Serevent) inhalers; and
 - b. eformoterol fumarate (Oxis and Foradil) inhalers to the net level of subsidy for the salmeterol (Serevent) inhalers.

These changes were the subject of consultation letters dated 30 August 2011 and 21 September 2011.

The reduction in subsidy will result in manufacturer's surcharges for Symbicort Turbuhaler, Vannair, Oxis Turbuhaler and Foradil should the supplier not reduce their prices to match the new subsidies. Alternative fully funded products will include fluticasone with salmeterol (Seretide, Seretide Accuhaler) and salmeterol (Serevent and Serevent Accuhaler).

To assist the implementation of these changes Symbicort Turbuhaler and Oxis Turbuhaler will remain fully funded for existing patients (patients dispensed Symbicort Turbuhaler or Oxis Turbuhaler prior to 1 July 2011) until 1 February 2012. Repeat dispensings for prescriptions with a first dispensing before 1 February 2012 will also be fully funded. This will give clinicians and patients time to make a change to fully funded pharmaceuticals in the event that the supplier does not reduce their prices and patients wish to receive a fully funded product.

Details of the decisions

Special Authority criteria for combination inhalers

From 1 February 2012 the Special Authority for the inhaled corticosteroids with long-acting beta-adrenoceptor agonists combination inhalers (SA0958) will be amended as follows (changes in bold and strike-through):

Initial Application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 Patient is a child under the age of 12; and
 - ~~1.2 Both:~~
 - ~~Has, for 3 months or more, been treated with:~~
 - ~~1.2.1 An inhaled long-acting beta-adrenoceptor agonist; and~~
 - ~~1.2.2 Inhaled corticosteroids at a dose of at least 400 mcg per day beclomethasone or budesonide, or 200 mcg per day fluticasone; and~~
 - 1.2 Has been treated with inhaled corticosteroids of at least 400 mcg per day beclomethasone or budesonide, or 200 mcg per day fluticasone; and**
 - 1.3 The prescriber considers that the patient would receive additional clinical benefit from switching to a combination product; or
- 2 All of the following:
 - 2.1 Patient is over the age of 12; and
 - ~~2.2 Both:~~
 - ~~Has, for 3 months or more, been treated with:~~
 - ~~2.2.1 An inhaled long-acting beta-adrenoceptor agonist; and~~
 - ~~2.2.2 Inhaled corticosteroids at a dose of at least 800 mcg per day beclomethasone or budesonide, or 500 mcg per day fluticasone; and~~
 - 2.2 Has been treated with inhaled corticosteroids of at least 800 mcg per day beclomethasone or budesonide, or 500 mcg per day fluticasone; and**
 - 2.3 The prescriber considers that the patient would receive additional clinical benefit from switching to a combination product.

Renewal only from a relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Flixotide Accuhaler

An agreement with GlaxoSmithKline has been approved which will result in the following:

- Fluticasone 100 µg and 250 µg (Flixotide Accuhaler) will be fully funded by an ex-manufacturer price decrease from 1 February 2012 in Section B and Part II of Section H of the Pharmaceutical Schedule as follows (prices and subsidies are ex-manufacturer, exclusive of GST):

Chemical	Presentation	Brand	Pack size	Current subsidy (price)	New price and subsidy
Fluticasone	Powder for inhalation, breath activated 100 µg	Flixotide Accuhaler	60 dose OP	\$7.50 (\$13.87)	\$7.50
Fluticasone	Powder for inhalation, breath activated 250 µg	Flixotide Accuhaler	60 dose OP	\$13.60 (\$24.51)	\$13.60

- Fluticasone 50 µg (Flixotide Accuhaler) will be fully funded by an increase in subsidy from 1 February 2012 in Section B of the Pharmaceutical Schedule as follows (price and subsidy are ex-manufacturer, exclusive of GST):

Chemical	Presentation	Brand	Pack size	Current subsidy (price)	New price and subsidy
Fluticasone	Powder for inhalation, breath activated 50 µg	Flixotide Accuhaler	60 dose OP	\$5.10 (\$7.50)	\$7.50

Note: the agreement with GlaxoSmithKline includes additional confidential rebates for Seretide and Seretide Accuhaler.

Subsidy changes

The subsidies for budesonide with eformoterol (Symbicort Turbuhaler and Vannair) and eformoterol fumarate (Oxis Turbuhaler and Foradil) will be reduced to the level of the subsidies for fluticasone and salmeterol (all prices are current ex-manufacturer's price, exclusive of GST). This will occur on 1 February 2012 and 1 July 2012 as shown below. In the event that the supplier does not reduce the prices of their products to match the new subsidies, a manufacturer's surcharge would apply (**Note: a mark-up, including GST, would apply to any manufacturer's surcharge**).

Pharmaceutical	Brand	Presentation	Pack size	New Subsidies (Current prices)	
				1 Feb 2012	1 July 2012
Budesonide 100 µg with eformoterol 6 µg	Symbicort Turbuhaler 100/6	Powder for inhalation	120 dose OP	\$29.54 (\$55.00)	\$26.49 (\$55.00)
Budesonide 200 µg with eformoterol 6 µg	Symbicort Turbuhaler 200/6	Powder for inhalation	120 dose OP	\$34.85 (\$60.00)	\$31.25 (\$60.00)
Budesonide 400 µg with eformoterol 12 µg	Symbicort Turbuhaler 400/12	Powder for inhalation	60 dose OP	\$34.85 (\$60.00)	\$31.25 (\$60.00)
Budesonide 100 µg with eformoterol 6 µg	Vannair	Aerosol inhaler	120 dose OP	\$29.52 (\$33.96)	\$26.49 (\$33.96)
Budesonide 200 µg with eformoterol 6 µg	Vannair	Aerosol inhaler	120 dose OP	\$34.85 (\$40.06)	\$31.25 (\$40.06)
Eformoterol fumarate 6 µg	Oxis Turbuhaler	Powder for inhalation	60 dose OP	\$11.51 (\$16.90)	\$10.32 (\$16.90)
Eformoterol fumarate 12 µg	Foradil	Powder for Inhalation	60 dose	\$23.02 (\$35.80)	\$20.64 (\$35.80)

The following products will be fully funded from 1 February 2012:

Inhaled Corticosteroids

- Beclomethasone dipropionate aerosol inhalers (Beclazone)
- Budesonide powder for inhalation (Budenocort and Pulmicort Turbuhaler)
- Fluticasone aerosol inhaler (Flixotide) and powder for inhalation (Flixotide Accuhaler)

Long-Acting Beta-Adrenoceptor Agonists

- Salmeterol aerosol inhaler (Serevent) and powder for inhalation (Serevent Accuhaler)

Combination Inhalers

- Fluticasone with salmeterol aerosol inhalers (Seretide) and powder for inhalation (Seretide Accuhaler)

The current additional subsidy for existing patients (patients who had been dispensed Symbicort Turbuhaler or Oxis Turbuhaler prior to 1 July 2011) will be extended to 1 February 2012. In the event that the suppliers do not reduce the prices of Symbicort Turbuhaler, Vannair, Oxis Turbuhaler and/or Foradil, PHARMAC will also fully fund repeat prescriptions where a first dispensing has occurred before 1 February 2012 - this will assist in the transition to fully funded products by allowing patients time to obtain a new prescription should they wish to have a fully funded product.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 28 September 2011 were considered in their entirety in making a decision on the proposed changes.

Most responses were supportive of the proposals. This was particularly evident in regard to the removal of the requirement for three months treatment with separate ICS and LABA inhalers prior to the use of a combination inhaler. The following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Some responders expressed concern that the only product registered for maintenance and reliever therapy (SMART) may not be fully funded.	In February 2010, the Respiratory Subcommittee of PTAC recommended against amending the restrictions applying to budesonide with eformoterol to include the SMART regimen.
Some responders were concerned that the proposal reduces the options for patients to have access to a range of fully funded combination products which may adversely affect their health management.	PHARMAC noted these concerns but considered that, in the event that the suppliers do not reduce their prices, a range of fully funded medications and devices would remain available.
One respondent queried the application of parity pricing to net subsidy levels.	The issues raised were considered prior to making a decision regarding parity pricing.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.