

## APPENDIX 3: PHARMAC ACCESS CRITERIA

The Pharmaceutical Management Agency lists the following access criteria in its August 2002 update of the Pharmaceutical Schedule. Pharmaceutical Schedule updates are available at [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

### Inhaled corticosteroids - nebuliser solution

BUDESONIDE

Note: The cost of nebuliser therapy greatly exceeds other inhaled forms. Steroid nebulising solution can cause cataract formation.

Nebuliser soln, 500 µg/ ml, 2 ml - Special Authority

PULMICORT

Special Authority - Hospital pharmacy

- a) Only for children under 2 years of age or children with major physical or intellectual disabilities who lack the necessary coordination to use aerosols with a spacer device.
- b) Specialist must make application – paediatrician/respiratory physician.

### Inhaled beta-adrenoceptor agonists - metered dose inhalers

#### Low dose

SALBUTAMOL

Available on a PSO

Aerosol inhaler, 100 µg/ dose CFC-free

Aerosol inhaler, 100 µg/ dose CFC-free

Aerosol inhaler, 100 µg/ dose

#### High dose

SALBUTAMOL

Available on a PSO

Aerosol inhaler, 200 µg/ dose

FENOTEROL HYDROBROMIDE

Aerosol inhaler, 100 µg/ dose

Aerosol inhaler, 200 µg/ dose

Special Authority - Retail pharmacy:

- a) Approval for subsidy will be granted if:
  - the patient has been on the product prior to 1 August 1990 (when it was removed from the Pharmaceutical Schedule)
  - alternatives (salbutamol & terbutaline) have been tried
  - the patient has asthma or chronic obstructive airways disease (COAD).
- b) The dose must be provided on the application.

### Inhaled beta-adrenoceptor agonists - breath activated devices

#### Medium dose

SALBUTAMOL - Available on a PSO

Aerosol inhaler, 100 µg/ dose, breath activated

Powder for inhalation, 50 µg/ dose, breath activated

## Inhaled beta-adrenoceptor agonists - long-acting

### Metered dose inhalers

SALMETEROL - Special Authority

Aerosol inhaler, 25 µg/ dose

*Breath activated devices*

EFORMOTEROL FUMARATE

Powder for inhalation, 6 µg/ dose, breath activated – Subsidy by endorsement

Subsidy is available for patients with poorly controlled asthma where:

- a) at least three months of 750 µg or more daily of inhaled beclomethasone or budesonide (or 400 µg of fluticasone) for adults has been used; or
- b) at least three months of 400 µg or more daily of inhaled beclomethasone or budesonide (or 200 µg of fluticasone) for children 12 years or older has been used.

The prescription must be endorsed accordingly. We recommend that the words used to indicate eligibility are “poor control with ICS” or “certified condition”.

BUDESONIDE WITH EFORMOTEROL - Special Authority

Powder for inhalation 100 µg with eformoterol fumarate 6 µg

Powder for inhalation 200 µg with eformoterol fumarate 6 µg

EFORMOTEROL FUMARATE - Special Authority

Powder for inhalation, 12 µg/ dose, and monodose device

Powder for inhalation, 12 µg/ dose, breath activated

SALMETEROL - Special Authority

Powder for inhalation, 50 µg/ dose, 4 doses/ disk

Powder for inhalation, 50 µg/ dose, breath activated

Special Authority - Retail pharmacy for eformoterol fumarate (12 µg/ dose), eformoterol fumarate with budesonide and salmeterol.

- a) Special Authority criteria either under point I (in its entirety), or point II (in its entirety), or point III (in its entirety) must apply before patients have access to subsidy.
- b) Special Authority approvals (CHEM numbers) are interchangeable among all presentations of inhaled long-acting  $\beta_2$ -agonists and eformoterol fumarate with budesonide.
- c) Applications for Special Authority to be made by general practitioners or an appropriate specialist.
- d) Approvals valid for two years.
- e) Patients are to be reviewed at least at six months to assess compliance and effectiveness of therapy.
- f) Applications to be made on a PHARMAC approved form.
- g) The re-application criteria under each point below (I, II or III) are:
  - (1) compliance (prescriber determined) with medication; and
  - (2) improved asthma symptom control.

- h) Children who turn 12, and are stabilised on an inhaled LABA, are not required to try Oxis Turbuhaler 6 µg in order to have continued access to their original inhaled LABA.
- I) Serevent MDI, Serevent Diskhaler, Serevent Accuhaler, Foradil, Oxis Turbuhaler 12 µg, Symbicort Turbuhaler Subsidy is available for:
- children with poorly controlled asthma under the age of 12 who required at least three months of 400 µg or more daily inhaled beclomethasone or budesonide (or 200 µg or more of fluticasone); or
  - adults with poorly controlled asthma who required at least three months of 1500 µg or more daily of inhaled beclomethasone or budesonide (or 750 µg or more of fluticasone).
- II. Serevent MDI, Serevent Diskhaler, Serevent Accuhaler Subsidy is available for patients with poorly controlled asthma aged 12 years and over, under the following criteria:
- at least three months of 750 µg or more daily of inhaled beclomethasone or budesonide (or 400 µg of fluticasone) for adults, or 400 µg or more daily inhaled beclomethasone or budesonide (or 200 µg of fluticasone) for children 12 years or older has been used; and
  - patients either:
    - are hypersensitive to eformoterol; or
    - have developed a product related adverse event that resolved on cessation and recurred on re-challenge with Oxis Turbuhaler 6 µg; or
    - after a six week trial of Oxis Turbuhaler 6 µg (with doses of 12–24 µg/ day) failed to show evidence of improved asthma control.
- III. Serevent MDI and spacer (with or without mask)

Subsidy is available in rare circumstances for patients with poorly controlled asthma aged 12 years and over, under the following criteria:

- have documented serious mental or physical\* disability who are incapable of being taught to use the appropriate breath activated device; and
- at least three months of 750 µg or more daily of inhaled beclomethasone or budesonide (or 400 µg of fluticasone) for adults, or 400 µg or more daily inhaled beclomethasone or budesonide (or 200 µg of fluticasone) for children 12 years or older has been used.

Applications must be made on a PHARMAC approved form, which contains a free text box for “Turbuhaler failures” where the nature of the documented serious mental or physical disability is to be recorded.

\*Hand grips for the Turbuhaler are available free of charge from AstraZeneca for patients with problems with manual dexterity.

### Inhaled beta-adrenoceptor agonists - nebuliser solutions

#### Low dose

SALBUTAMOL - Available on a PSO

Nebuliser soln, 1 mg/ ml, 2.5ml

#### High dose

SALBUTAMOL - Available on a PSO

Nebuliser soln, 2 mg/ ml, 2.5ml

### Inhaled anticholinergic agents - nebuliser solutions

#### Low dose

IPRATROPIUM BROMIDE - Available on a PSO

Nebuliser soln, 250 µg/ ml, 1ml

#### High dose

IPRATROPIUM BROMIDE - Available on a PSO

Nebuliser soln, 500 µg/ 2ml, 2ml

Inhaled beta-adrenoceptor agonist and anticholinergic agents - metered dose inhalers

FENOTEROL HYDROBROMIDE WITH IPRATROPIUM BROMIDE - Special Authority

Aerosol inhaler, 100 µg with ipratropium bromide, 40 µg/ dose

Special Authority - Retail pharmacy:

- a) Approval for subsidy will be granted if:
- the patient has been on the product prior to 1 August 1990 (when it was removed from the Pharmaceutical Schedule)
  - alternatives (salbutamol & terbutaline) have been tried
  - the patient has asthma or chronic obstructive airways disease (COAD).
- b) The dose must be provided on the application.

### **Inhaled beta-adrenoceptor agonist and anticholinergic agents - nebuliser solution**

SALBUTAMOL WITH IPRATROPIUM BROMIDE - Available on a PSO

Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg/ 2.5 mlvial, 2.5ml

### **Beta-adrenoceptor agonists - injection**

SALBUTAMOL

Inj 500 µg/ ml, 1 ml - Available on a PSO

### **Theophylline derivatives**

AMINOPHYLLINE

‡ Oral liq 25 mg/ ml - Retail pharmacy-specialist

Oral liquid is:

- a) Retail pharmacy-specialist; and
- b) Prescriptions must be written by a paediatrician or paediatric cardiologist; or
- c) On the recommendation of a paediatrician or paediatric cardiologist.

Inj 25 mg/ ml, 10 ml - Available on a PSO.