

4 May 2009

Proposal relating to valaciclovir, bupropion and various respiratory products

PHARMAC is seeking feedback on a proposal relating to a provisional agreement signed with GlaxoSmithKline for a number of products. In summary, the proposal would result in:

- the listing of valaciclovir (Valtrex), a treatment for herpesvirus infection, under Special Authority criteria;
- the listing of bupropion (Zyban) for smoking cessation, without prescribing restrictions; and
- the listing of a large volume spacer (Volumatic) available on wholesale supply order.

The proposal would also result in changes to the commercial arrangement for fluticasone (Flixotide), salmeterol (Serevent) and fluticasone with salmeterol (Seretide), although the listings of these products in the Pharmaceutical Schedule would not be substantially affected and they would remain fully funded.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by 4 pm on **Friday, 15 May 2009** to:

Sean Dougherty
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: sean.dougherty@pharmac.govt.nz

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision.

Details of the proposal and background information are set out on the following 2 pages.

Details of the proposal

Bupropion

- Bupropion would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2009 at the following price and subsidy (ex-manufacturer, exclusive of GST):

Chemical	Formulation	Brand	Pack size	Price / subsidy
Bupropion hydrochloride	Tab 150 mg modified-release	Zyban	30	\$65.00

- Bupropion would be listed without Special Authority or endorsement restrictions.
- Zyban would be protected from subsidy reduction until 1 January 2012, and from delisting until 1 January 2014.
- A confidential rebate would apply to Zyban.

Valaciclovir

- Valaciclovir would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2009 at the following price and subsidy (ex-manufacturer, exclusive of GST):

Chemical	Formulation	Brand	Pack size	Price / subsidy
Valaciclovir	Tab 500 mg	Valtrex	30	\$102.72

- Valaciclovir would be subject to the following Special Authority restriction in Section B of the Pharmaceutical Schedule:

Special Authority for Subsidy

Initial application – (recurrent genital herpes) from any practitioner. Approvals valid for 12 months where the patient has genital herpes with 2 or more breakthrough episodes in any 6 month period while treated with aciclovir 400 mg twice daily.

Renewal – (recurrent genital herpes) from any practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application – (ophthalmic zoster) from any practitioner. Approvals valid without further renewal unless notified where the patient has previous history of ophthalmic zoster.

Initial application – (CMV prophylaxis) from any practitioner. Approvals valid for 3 months where the patient has undergone organ transplantation.

- Valtrex would be protected from subsidy reduction until 1 January 2012, and from delisting until 1 January 2014.

Respiratory products

- The Volumatic brand of large volume spacers would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2009 at the following price and subsidy (ex-manufacturer, exclusive of GST):

Chemical	Formulation	Brand	Pack size	Price / subsidy
Spacer device	800 mL	Volumatic	1	\$8.50

- Volumatic would only be available on a wholesale supply order (WSO).
- The age restriction that currently applies to spacer devices would be removed.
- The prices and subsidies of fluticasone (Flixotide, Flixotide Accuhaler), salmeterol (Serevent, Serevent Accuhaler) and fluticasone with salmeterol (Seretide, Seretide Accuhaler) would be unchanged, and these products would be protected from delisting and subsidy reduction until 1 July 2014.
- Confidential rebates would apply to Flixotide, Flixotide Accuhaler, Seretide, Seretide Accuhaler, Seretide, Seretide Accuhaler and Volumatic.
- The Special Authority restriction that applies to fluticasone with salmeterol (and that also applies to budesonide with eformoterol) would be amended to allow for applications to be made by any practitioner; at present only General Practitioners and specialists can make applications – this change would allow Nurse Prescribers to make applications as well.

Background

Bupropion is indicated for the treatment of nicotine dependence. Current fully funded treatments for smoking cessation include nicotine replacement therapy and nortipyline. This proposal would provide bupropion as another fully funded option for treating nicotine dependence. The commercial arrangement with GlaxoSmithKline, which includes a rebate on Zyban and a range of other products, would enable the funding of this agent at a level that would be consistent with the costs of other funded smoking cessation treatments. PTAC has previously recommended that bupropion be listed with a low priority.

Valaciclovir is an antiviral agent indicated for the treatment of herpes zoster and herpes simplex infections, as well as prophylactic treatment for cytomegalovirus (CMV) infection. Valaciclovir is the pro-drug of acyclovir and has a greater bioavailability (about 55% greater) than acyclovir. This increased bioavailability may be beneficial for patients who currently experience breakthrough whilst being treated with conventional acyclovir. Valaciclovir has previously been listed in the Pharmaceutical Schedule, but was discontinued in 1999.

Large volume spacers are used in conjunction with aerosol inhalers for the management of asthma and chronic obstructive pulmonary disease. While medium volume (230 mL) spacers are currently subsidised, some patients may find benefit from a larger volume product. At present Volumatic spacers are distributed by GSK, and the listing of these products on the Schedule would formalise this arrangement.

There is currently an age restriction applying to the use of spacer devices, and we are proposing to remove this in line with a recommendation by the Respiratory Subcommittee of PTAC.