



Non-Insured Health Benefits

Drug Bulletin

November 2002

The NIHB Program provides supplementary health benefits, including prescription and non-prescription drugs, for registered Indians, and recognized Inuit and Innu throughout Canada.

Visit our Web Site at: www.hc-sc.gc.ca/fnihb/nihb

ADDITIONS TO THE DRUG BENEFIT LIST (OPEN BENEFITS)

(Effective August 1, 2002)

**1. Abacavir sulfate/lamivudine/zidovudine, Tablet,
300 mg/150 mg/ 300mg
(Trizivir™ - GlaxoSmithKline Inc.)**

Trizivir™ is a combination product for the treatment of Human Immunodeficiency Virus (HIV) infection in adult patients.

**2. Nateglinide, Tablet, 60 mg, 120 mg, 180 mg
(Starlix® - Novartis Pharmaceuticals Canada Inc.)**

Starlix® is an oral antidiabetic agent indicated as monotherapy in addition to diet and exercise to lower blood sugar in patients with type 2 diabetes who are not satisfactorily controlled by diet and exercise alone and in combination with metformin in patients not controlled satisfactorily on diet, exercise, and either nateglinide or metformin alone.

NEW LIMITED USE BENEFITS (prior approval required)

(Effective August 1, 2002)

**1. Alfuzosin hydrochloride, Prolonged- Release
Tablet, 10 mg
(Xatral® -Sanofi-Synthelabo Canada Inc.)**

Coverage will be provided for the treatment of benign prostatic hyperplasia (BPH) in patients who cannot tolerate or have not responded to other alpha- adrenergic blockers.

**2. Botulinum toxin type A, Injection, 100 Unit/vial,
DIN 01981501
(Botox® - Allergan Inc.)**

Coverage will be provided for the treatment of focal dystonias and hyperhidrosis. More specific criteria are being developed and will be made available in a later bulletin. Botulinum toxin for cosmetic purposes will not be covered.

NEW LIMITED USE BENEFITS (cont'd)

**3. Budesonide/formoterol fumarate dihydrate, Turbuhaler,
Powder for inhalation, 100 mcg/6 mcg, 200 mcg/6 mcg
(Symbicort® - AstraZeneca Canada Inc.)**

Coverage will be provided for the treatment of reversible obstructive airway disease in patients who are not adequately controlled on medium doses of inhaled corticosteroids (e.g., fluticasone 250 - 500 mcg daily, or the equivalent) as a sole agent and require addition of a long-acting beta agonist. Patients using this combination product must also have access to a short-acting bronchodilator for symptomatic relief.

**4. Tacrolimus, Ointment, 0.03%, 0.1%,
(Protopic® - Fujisawa Canada Inc.)**

Coverage will be provided for patients who have failed topical corticosteroid therapy or have experienced side effects from such treatment. It must be prescribed by a dermatologist.

(Effective December 1, 2002)

**5. Tolterodine L-tartrate, Extended Release
Capsule, 2 mg, 4 mg
(Unidet™ - Pharmacia Canada Inc.)**

Coverage will be provided for the symptomatic relief of patients with an overactive bladder with symptoms of urinary frequency, urgency or urge incontinence or any combination of these in patients who have failed on or are intolerant of therapy with oxybutynin

"Our mission is to help the people of Canada maintain and improve their health"

NIHB DECISION NOT TO ADD THE FOLLOWING DRUGS TO THE NIHB DRUG BENEFIT LIST AFTER REVIEW BY THE FEDERAL PHARMACY AND THERAPEUTICS COMMITTEE:

Alendronate, Tablet, 70 mg (Fosamax®- Merck Frosst Canada Ltd.)

Betamethasone dipropionate 0.5mg/g & calcipotriol 50 mcg/g, Ointment, (Dovobet™ - Leo Pharma Inc.)

Desloratadine, Tablet, 5 mg (Aerius™ - Schering Canada Inc.)

Insulin aspart , Injection, 100 units/ml, (NovoRapid® - Novo Nordisk Canada Inc.)

Orlistat, Capsule, 120 mg, (Xenical - Hoffman - La Roche Ltd.) - for New Indication ; for use in combination with anti-diabetic agents to improve blood glucose control in overweight or obese type 2 diabetes patients who are inadequately controlled on diet, exercise, and one or more of a sulphonylurea, metformin or insulin.

Testosterone, Gel, 1%, (Androge™ - Solvay Pharma Inc.)

NIHB DEFERRED DECISION ON LISTING

Infliximab, Injection, 100 mg/vial, (Remicade™ - Schering Canada Inc.)

CHANGES IN NIHB BENEFIT STATUS

Tamsulosin hydrochloride, Sustained Release Capsule, 0.4 mg, (**Flomax® - Boehringer Ingelheim (Canada Ltd.)**) will become a **LIMITED USE BENEFIT**, effective January 1, 2003. The criteria for use is for the treatment of benign prostatic hyperplasia (BPH) in patients who do not tolerate or have not responded to other alpha adrenergic blockers. This is consistent with the NIHB decision in November 1998 to list Flomax® as a limited use benefit. Due to a systems problem, Flomax® had been listed as a full benefit.

Brimonidine tartrate, Ophthalmic Solution , 0.2%, (**Alphagan™ - Allergan Inc.**), will be listed as an **OPEN BENEFIT**, effective July 1, 2002.

CHANGE TO NIHB BULLETIN JULY 2002

The following wording has been removed from the bulletin regarding **mirtazapine tablet, 30 mg (Remeron® - Organon)** description:

No published trials have shown the place of mirtazapine in antidepressant therapy.

Health Canada timelines for the elimination of chlorofluorocarbons (CFC)- containing products¹

On March 13, 2002, Health Canada released a schedule by which CFC-containing pharmaceuticals are to be eliminated. The phase-out process is being done on a drug-by-drug basis starting with salbutamol.

The phase-out schedule will prohibit the use of CFCs as shown below:

| Effective Date | Phase-out Component |
|-----------------|---|
| July 1, 2002 | the production and importation of MDIs* containing salbutamol |
| January 1, 2003 | the sale of MDIs containing salbutamol |
| January 1, 2004 | the production and importation of MDIs containing corticosteroids |
| January 1, 2005 | the production and importation of all other MDIs |

* Metered-Dose Inhalers

1. Registration SOR/2002-100 In: Canada Gazette Part II;136(6):581-590

Health Canada Advisory Website:

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advis_tpd_bgt_d_e.html

Health Canada Adverse Reaction Information Website:

<http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/adr.html>