Health Canada Santé Canada

Non-Insured Health Benefits

Drug Bulletin

September 2005

The Non-Insured Health Benefits (NIHB) Program provides supplementary health benefits, including prescription and non-prescription drugs, for registered First Nations and recognized Inuit throughout Canada.
Visit our Website at: www.healthcanada.gc.ca/nihb

ADDITIONS TO THE DRUG BENEFIT LIST

OPEN BENEFITS

(Effective September 1, 2005)

1. Leuprolide acetate, Injection, 7.5mg, 22.5mg and 30mg (Eligard® - Sanofi-Synthelabo Canada Inc.)

Eligard® is indicated for the palliative treatment of advanced prostate cancer.

2. Anastrozole, Tablet, 1mg (Arimidex® - AstraZeneca Canada Inc.)

Arimidex® is indicated for the adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer.

3. Eprosartan mesylate/Hydrochlorothiazide, Tablet, 600mg and 12.5mg (Teveten® Plus - Solvay Pharma Inc.)

Teveten® Plus is indicated for the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate. It is not indicated for initial therapy.

NEW LIMITED USE BENEFITS

(Prior approval required)
(Effective October 1, 2005)

1. Adalimumab, Injection, 40mg/vial, (Humira™ - Abbott Laboratories Limited)

Humira™ will be a limited use benefit for the treatment of reducing signs and symptoms, and inhibiting the progression of structural damage in adult patients with moderate to severe active rheumatoid arthritis (RA). Patients must be refractory to or intolerent of at least two potent disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate and leflunomide.

2. Norelgestromin/Ethinyl estradiol, Transdermal System, 6.0mg/0.60mg (Evra™ - Janssen-Ortho)

Evra™ transdermal system is indicated for the prevention of pregnancy. Evra™ will be a limited use benefit for patients who are intolerant to or unable to take oral contraceptives.

LIMITED USE BENEFITS - REVISED CRITERIA

(Prior approval required)
1. Ciprofloxacin HCl/Hydrocortisone, Otic Suspension, 2mg and 10mg (Cipro® HC - Alcon Canada Inc.)

The criteria for Cipro® HC will be revised as follows:

a) Failure to respond to other listed topical antibiotics, or
b) Contraindications to other listed topical antibiotics.

NEW INDICATIONS ADDED TO EXISTING LIMITED USE BENEFITS

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

Remicade® is indicated to reduce signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's Disease who have had an inadequate response to conventional therapy.

EXCEPTIONS

(Prior approval required)

The following drugs may be considered for reimbursement in special circumstances when the prescription is for a recognized clinical indication and dose which is supported by published evidence or authoritative opinion; and where there is significant evidence that the requested drug is superior to drugs already listed as Program benefits.

Canada

1. Methylphenidate hydrochloride, Extended-Release Tablet, 18mg, 36mg and 54mg (Concerta™ - Janssen-Ortho)

2. Moxifloxacin hydrochloride, Ophthalmic Solution, 0.5%, (Vigamox™ - Alcon)

3. Ciprofloxacin HCl and dexamethasone, Otic Suspension, 0.3% and 0.1% (Ciprodex® - Alcon)

4. Treprostinil sodium, Injection, 1mg/mL, 2.5mg/mL, 5mg/mL, and 10mg/mL (Remodulin™ - United Therapeutics Corporation)

5. Cinacalcet, Tablet, 30mg, 60mg, and 90mg (Sensipar™ - Amgen Canada Inc.)

6. Voriconazole, Tablet, 50mg and 200mg (Vfend™ - Pfizer Canada Inc.)

NIHB DECISION NOT TO ADD THE FOLLOWING DRUG PRODUCTS TO THE NIHB DRUG BENEFIT LIST AFTER REVIEW BY THE COMMON DRUG REVIEW (CDR) PROCESS AND THE FEDERAL PHARMACY AND THERAPEUTICS COMMITTEE (FP&T)

The following drugs will be excluded from the NIHB Program as recommended by the CDR and the FP&T because published evidence does not support the clinical value or cost of the drug relative to existing therapies, or there is insufficient clinical evidence to support coverage.

Of Note: The Appeal Process and the Emergency Supply Policy will not apply for the following drug products.

1. Ciprofloxacin, Extended Release Tablet, 500mg and 1000mg (Cipro XL™ - Bayer)

2. Butoconazole nitrate, Vaginal Cream, 2% (Gynazole-1® - Ferring)

3. Eletriptan hydrobromide, Tablet, 20mg and 40mg (Relpax™ - Pfizer)

NIHB DEFERRED DECISION ON LISTING

1. Risperidone, Powder for Suspension sustained-release, 25mg/vial, 37.5mg/vial, and 50mg/vial (Risperdal® Consta® - Janssen-Ortho)

2. Magnesium oxide, citric acid, sodium picosulphate, Powder for Solution (Pico-Salax™ - Ferring Inc.)

3. Dutasteride, Capsule, 0.5mg (Avodart™ - GlaxoSmithKline Inc.)

4. Alefacept, Powder for Solution, 15mg/vial (Amevive® - Biogen Canada Inc.)

5. Agalsidase beta lyophilized powder (Fabrazyme® - Genzyme Canada Inc.)

6. Agalsidase Alfa concentrate for solution for infusion, 1mg/mL (Replagal™ - Transkaryotic Therapies Inc.)

7. Miglustat, Capsule, 100mg (Zavesca™ - Actelion Pharmaceuticals Ltd.)

8. Teriparatide, Injection, 250mcg/mL (Forteo™ - Lily)

CHANGES IN BENEFIT STATUS

(Effective August 1, 2005)

Of Note: The Appeal Process and the Emergency Supply Policy will not apply for the following drug products.

1. Butorphanol tartrate nasal spray (Stadol™ NS and generics)

Stadol™ NS and generics will no longer be provided as exceptions under the NIHB Program. Effective August 1, 2005, Stadol™ NS and generics will be exclusions. The NIHB Program has been faxing letters to prescribers since April 2005 advising that the Program will no longer provide reimbursement effective August 1, 2005, in order to allow time for reassessment and to plan for alternative therapy.

2. Butalbital containing analgesics with and without codeine (Fiorinal®, Fiorinal® C ¼, Fiorinal® C ½ and generics)

Fiorinal®, Fiorinal® C ¼, Fiorinal® C ½ and generics will no longer be provided as exceptions under the NIHB Program. Effective August 1, 2005, Fiorinal®, Fiorinal® C ¼, Fiorinal® C ½ and generics will be exclusions. The NIHB Program has been faxing letters to prescribers since April 2005 advising that the Program will no longer provide reimbursement effective August 1, 2005, in order to allow time for reassessment and to plan for alternative therapy.

(Prior approval required)
(Effective October 1, 2005)

1. Tacrolimus (Prograf®)
Prograf® will change listing status from an open benefit to a limited use benefit for transplant therapy.

2. Cyclosporine (Neoral® and generics)
Neoral® and generics will change listing status from an open benefit to a limited use benefit for transplant therapy.

3. Mycophenolate mofetil (Cellcept®)
Cellcept® will change listing status from an open benefit to a limited use benefit for transplant therapy.

4. Fentanyl, Patch, 25, 50, 75 and 100 (Duragesic® - Janssen-Ortho)

Duragesic® will change listing status from an open benefit to a limited use benefit.

The Criteria for use will be as follows:

For the management of chronic pain in patients who are unresponsive or intolerant to at least one long-acting oral sustained released product, such as morphine, hydromorphone and oxycodone, despite appropriate dose titration and adjunctive therapy including laxatives and antiemetics.

BENEFITS DELISTED FROM THE NIHB DRUG BENEFIT LIST

Pfizer Canada Inc. has agreed to voluntarily suspend the sale and marketing of Bextra™ (Valdecoxib) tablets in Canada pending the submission of Bextra's benefit and risk assessment. As a result, Bextra™ (Valdecoxib) has been delisted as a benefit under the NIHB Program, effective April 8, 2005.

PROTON PUMP INHIBITORS (PPIs) REVIEW AND CHANGE IN CRITERIA

The NIHB Program is changing the formulary status and availability of selected PPIs. Implementation of this policy will be phased in effective October 1, 2005. Because available evidence indicates that these agents have the same clinical effect, there will be few exemptions to this new policy.

The new limited use criteria for PPIs is:

Lansoprazole 15 and 30mg (Prevacid®), Omeprazole 10 and 20mg (Losec®), Omeprazole Magnesium 10 and 20mg (Losec®), and Pantoprazole 40mg (Pantoloc®) will only be available as limited use benefits after patients have been tried for at least 60 days on Apo-Omeprazole® 20mg AND for at least 60 days on a therapeutic dose of Pariet® 10mg (for example, two tabs daily).

In addition, as a result of this policy change Esomeprazole 20mg and 40mg (Nexium®), Pantoprazole 20mg (Pantoloc®), and Rabeprazole 20mg (Pariet®) will no longer be reimbursed by the NIHB Program.

IMPORTANT DRUG SAFETY INFORMATION

The following is taken from the Therapeutic Products Directorate Website:

Important Safety Update: Potential effect of Depo-Provera® (medroxyprogesterone acetate injectable suspension, USP) on Bone Mineral Density (BMD) changes in adults and adolescents.

For further information and for other Health Canada advisories, please visit the Health Canada Website at:

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/index_e.html

NEW CHEMICAL ENTITY DRUGS UNDER REVIEW BY THE COMMON DRUG REVIEW

As of September 1, 2003, submissions for new chemical entities and new combination drug products are reviewed by the Common Drug Review (CDR) at the Canadian Coordinating Office of Health Technology Assessment (CCOHTA). The NIHB Program and other federal, provincial and territorial drug plans make listing decisions based on the Canadian Expert Drug Advisory Committee (CEDAC) recommendations and other specific relevant factors, such as mandate, priorities and resources.

For a list of drugs currently being reviewed through the Common Drug Review (CDR) process, please refer to the Canadian Coordinating Office of Health Technology Assessment (CCOHTA) website at:

www.ccohta.ca

Of Note: The Appeal Process and the Emergency Supply Policy will not apply for drug products under review by the CDR Process.