



February 2006

Non-Insured Health Benefits

First Nations and Inuit Health Branch

Drug Bulletin

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 Web Site at: www.healthcanada.gc.ca/nihb

BENEFIT DEFINITIONS

Open Benefits

Open benefits are the drugs listed in the NIHB Drug Benefit List (DBL) which do not have established criteria or prior approval requirements.

Limited use Benefits

Limited use drugs are those that have value in specific circumstances, or which have quantity and frequency limitations. For drugs in this category, specific criteria must be met to be eligible for coverage.

Not Added To Formulary

Drugs not added to formulary are those which are not listed in the NIHB DBL after review by the national Common Drug Review (CDR) process and/or the Federal Pharmacy and Therapeutics Committee (FP&T). These drugs will not be added to the NIHB drug list because published evidence does not support the clinical value or cost of the drug relative to existing therapies. Coverage may be considered in special circumstances upon receipt of a completed "Exception Drugs Request Form". These requests are reviewed on a case by case basis.

Exclusions

Certain drug therapies for particular conditions do not fall under the NIHB mandate and will not be provided as benefits under the NIHB Program (e.g., cosmetic and anti-obesity drugs). As well, certain 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, safety or cost of the drug relative to existing therapies, or there is insufficient clinical evidence to support coverage.

Note: The appeal process and the emergency supply policy will not apply to excluded drugs.

ADDITIONS TO THE DRUG BENEFIT LIST

OPEN BENEFITS

(Effective December 1, 2005)

1. Vitamin D, Tablet, 400IU & 1000IU (Generics)

(Effective January 1, 2006)

2. Drospirenone 3mg /Ethinyl estradiol 0.03mg, Tablet (Yasmin® 21 & 28 - Berlex Canada Inc.)

Yasmin® 21 and 28 are indicated for conception control.

3. Mirtazapine, Tablet, 15mg, 30mg and 45mg (Remeron®, Remeron RD® - Organon Canada Limited and generics)

Remeron® and Remeron RD® are indicated for the symptomatic relief of depressive illness.

NEW LIMITED USE BENEFITS

(Prior approval required)

(Effective March 1, 2006)

1. Peginterferon alfa-2a, Injection, 180mcg/vial and Ribavirin, Tablet, 200mg (Pegasys® RBV™ - Hoffman-LaRoche Limited)

2. Peginterferon alfa-2a, Injection, 180mcg/vial (Pegasys® - Hoffman-LaRoche Limited)

Pegasys® RBV™ and Pegasys® will be limited use benefits for the treatment of chronic hepatitis C in patients who are treatment naive, upon the written request of a hepatologist or other specialist in this area.

- a) For genotype 1, 4, 5 and 6 an initial 24 week supply will be approved. A further 24 week supply may be approved if patient has a viral reduction of at least 2

.../2

Disponible en français

logs or HCV is undetectable at 12 weeks (for a total of 48 weeks of treatment).

b) For genotype 2 or 3, initial coverage for a maximum of 24 weeks may be approved. Renewals will not be covered.

3. Mycophenolate Sodium, Tablet, 180mg and 360mg (Myfortic® - Novartis Pharmaceuticals Canada Inc.)
Myfortic® will be a limited use benefit for transplant therapy.

LIMITED USE BENEFITS - REVISED CRITERIA

1. Peginterferon alfa-2b, Powder for Solution, 50mcg/vial, 80mcg/vial, 100mcg/vial, 120mcg/vial and 150mcg/vial and Ribavirin, Capsule, 200mg (Pegetron™ - Scherring)

2. Peginterferon alfa-2b, Powder for Solution, 74mcg/vial, 118.4mcg/vial, 177.6mcg/vial and 222mcg/vial (Unitron PEG™ - Scherring)

The criteria for Pegetron™ and Unitron PEG™ will be revised as follows:

For the treatment of chronic hepatitis C in patients who are treatment naive, upon the written request of a hepatologist or other specialist in this area.

a) For genotype 1, 4, 5 and 6 an initial 24 week supply will be approved. A further 24 week supply may be approved if patient has a viral reduction of at least 2 logs or HCV is undetectable at 12 weeks (for a total of 48 weeks of treatment).

b) For genotype 2 or 3, initial coverage for a maximum of 24 weeks may be approved. Renewals will not be covered.

NOT ADDED TO FORMULARY

The following drugs products will not be added to the NIHB Drug Benefit List:

- 1. Risperidone, Powder for Suspension sustained-release, 25mg/vial, 37.5mg/vial, and 50mg/vial (Risperdal® Consta® - Janssen Ortho)**
- 2. Gatifloxacin, Ophthalmic Solution, 0.3% (Zymar™ - Allergan)**
- 3. Oxybutynin, Transdermal System, 36mg (Oxytrol™ - Paladin Labs Inc.)**

4. Amevive, Injection, 15mg/vial (Amevive™ - Biogen Idec Canada Inc.)

5. Teriparatide, Injection, 250mcg/mL (Forteo™ - Lilly)

The following indications will not be added to the NIHB Drug Benefit List:

1. Imiquimod, Cream, 5% (Aldara® - 3M Pharmaceuticals)

For the treatment of superficial basal cell carcinoma.

2. Darbepoetin alfa, Injection, 15mcg, 25mcg, 40mcg, 60mcg, 100mcg, 200mcg, 325mcg and 500mcg (Aranesp™ - Amgen Canada Inc.)

For the treatment of anemia in patients with nonmyeloid malignancies, where anemia is due to the effect of concomitantly administered chemotherapy.

3. Etanercept, Powder for Injection, 25mg/vial (Enbrel® - Amgen Canada Inc.)

For reducing signs and symptoms of active ankylosing spondylitis.

EXCLUSIONS

1. Paroxetine HCl, Controlled-Release Tablet, 12.5mg and 25mg (Paxil CR™ - GlaxoSmithKline Inc.)

2. Ketorolac tromethamine, Ophthalmic Solution, 0.4% (Acular LS® - Allergan)

NIHB DEFERRED DECISION ON LISTING

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

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

3. Pegfilgrastim, Injection, 6mg/syringe (Neulasta™ - Amgen Canada Inc.)

4. Fosamprenavir calcium, Tablet, 700mg and Oral Suspension 50mg/mL (Telzir™ - GlaxoSmithKline)

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. Laronidase, Solution for Injection (Aldurazyme® - Genzyme Canada Inc.)

9. Enfuvirtide, Lyophilized Powder (Fuzeon® - Hoffman-LaRoche Limited)