Health Canada Santé Canada

June 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 April 1, 2006)

1. Fluticasone Propionate, Cream, 0.05% (Cutivate® - GlaxoSmithKline Consumer Healthcare Inc.)
Cutivate® is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

2. Abacavir Sulfate/Lamivudine, Tablet, 600mg/300mg (Kivexa™ - GlaxoSmithKline Shire Biochem)
Kivexa™ is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults.

3. Fluvastatin Sodium, Extended Release Tablets, 80mg (Lescol® XL - Novartis Pharmaceuticals Canada Inc.)
Lescol® XL is indicated as an adjunct to diet in the treatment of elevated total cholesterol, low density lipoprotein cholesterol, triglycerides and Apo B levels in patients with primary hypercholesterolemia and mixed hyperlipidemia.

NEW LIMITED USE BENEFITS

(Prior approval required)
(Effective May 1, 2006)

1. Dutasteride, Capsule, 0.5mg (Avodart™ - GlaxoSmithKline Inc.)
a) For treatment of Benign Prostatic Hyperplasia (BPH) in patients who do not tolerate or have not responded to

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an alpha-adrenergic blocker;
or
b) For use in combination therapy when monotherapy with an alpha-blocker is not sufficient.

2. Pegfilgrastim, Solution, 10mg/mL (Neulasta® - Amgen Canada Inc.)
a) To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive antineoplastic drugs with curative intent;
and
b) Where access to a health care facility is problematic.

LIMITED USE BENEFITS - REVISED CRITERIA

(Prior Approval Required)
(Effective May 1, 2006)

Tiotropium Bromide Monohydrate, Capsule, 18mcg (Spiriva® - Boehringer Ingelheim Canada Limited)
For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), in patients who continue to be symptomatic after an adequate trial (2-4 months) of ipatropium, at a dose of 12 puffs daily.

CHANGES IN BENEFIT STATUS

(Effective May 1, 2006)

Bisoprolol Fumarate, Tablet, 5mg and 10mg (Monocor® - Biovail Pharmaceuticals Canada and Generics)
Monocor® and generics will change listing status from an exception benefit to an open benefit.

NOT ADDED TO FORMULARY

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

1. Enfuvirtide, Lyophilized Powder, 108mg (Fuzeon® - Hoffman-La Roche Limited)

2. Atomoxetine HCl, Capsule, 10mg, 18mg, 25mg, 40mg and 60mg (Strattera™ - Eli Lilly Canada Inc.)

3. Insulin Glargine, Injectable, 100IU/mL (Lantus® - Aventis Pharma Inc.)

4. Memantine HCl, Tablet, 10mg (Ebixa® - Lundbeck Canada Inc.)

5. Bisacodyl/Docusate Sodium, Tablet, 5mg/50mg (Gentlax-S® - Purdue Pharma)

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

Imiquimod, cream, 5% (Aldara® - 3M Pharmaceuticals)
For the treatment of actinic keratosis.

NIHB DEFFERRED DECISION ON LISTING

1. Magnesium Oxide, Citric Acid, Sodium Picosulphate, Powder for Solution, 3.5gm, 12gm and 10mg (Pico -Salax™ - Ferring Inc.)

2. Erlotinib HCl, Tablet, 100mg and 150mg (Tarceva™ - Hoffman - La Roche Limited)

3. Quinagolide HCl, Tablet, 0.075mg and 0.15mg (Norprolac® - Ferring Pharmaceuticals Inc.)

PRIOR APPROVAL FOR DICLOFENAC

The NIHB Program reviewed a submission request for diclofenac topical preparation and concluded that the evidence base for the utilization of diclofenac in a topical form was not sufficient to recommend the addition of this product to the NIHB Drug Benefit List. Therefore, a pharmacist receiving a prescription to dispense a topical preparation containing diclofenac must obtain prior approval from the National Drug Exception Centre before dispensing the preparation. This applies even when diclofenac oral tablets are the primary ingredient in the compound. It is important to remember that a pharmacist will not receive payment for any compounds that replicate a drug product already available on the market. Please note that all claims submitted to the NIHB Program are subject to audit.

IMPLEMENTATION OF THE NEW "NE" WARNING MESSAGE

Please be advised that the implementation of the new "NE" warning message (Potential Overuse/Abuse Indicated) scheduled for December 16, 2005 as announced in the Winter 2005 - 2006 NIHB Pharmacy Newsletter was delayed until April 28, 2006.

The purpose of this warning code is to provide pharmacists with additional information that a potential drug entity misuse/abuse situation may exist.

Upon implementation of the "NE" warning message,

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the CPhA warning message 'Potential Overuse/Abuse Indicated' will be returned for POS claims that meet the following criteria:

a) Use of three (3) or more different opioid narcotic drug entities.
b) Use of three (3) or more different benzodiazepine drug entities.
c) Use of a combination of three (3) or more opioid narcotics drug entities and three (3) or more benzodiazepines drug entities.

First Canadian Health (FCH) apologizes for any inconvenience that the delay in implementing the "NE" warning message may have caused.

Should you have any questions on this subject, please contact the FCH NIHB Toll-Free Inquiry Centre at **1-888-511-4666.**