Health Canada Santé Canada

Non-Insured Health Benefits

Drug Bulletin

November 2004

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.hc-sc.gc.ca/fnihb/nihb

ADDITIONS TO THE DRUG BENEFIT LIST

OPEN BENEFITS

(Effective October 1, 2004)

1. Brimonidine tartrate/timolol maleate, Ophthalmic Solution, 0.2% & 0.5% (Combigan® - Allergan Inc.)

Combigan® is indicated for the control of intraocular hypertension in patients with chronic open-angle glaucoma or ocular hypertension.

2. Almotriptan malate, Tablet, 6.25mg and 12.5mg (Axert - Janssen-Ortho Inc.)

Axert® is indicated for the acute treatment of migraine with or without aura in adults.

3. Risperidone orally disintegrating, Tablet, 0.5mg, 1mg and 2mg (Risperdal-M - Janssen-Ortho Inc.)

Risperdal-M is indicated for the acute treatment and maintenance treatment of schizophrenia and related psychotic disorders.

NEW LIMITED USE BENEFITS

(Prior approval required)

(Effective January 1, 2005)

1. Ezetimibe, Tablet, 10mg (Ezetrol™ - Merck Frosst/Schering Pharmaceuticals)

Ezetrol™ will be a limited use benefit for the treatment of primary hypercholesterolemia either alone or in combination with a "statin".

a) For use in combination with a HMG-CoA reductase inhibitor ('statin') in patients with hypercholesterolemia who have not reached target LDL levels despite the use of maximally tolerated "statin" doses.

b) For use as monotherapy in the management of hypercholesterolemia in patients intolerent to HMG-CoA reductase inhibitors.

2. Levetiracetam, Tablet, 250mg, 500mg and 750mg (Keppra® - UCB Pharma Inc [Lindbeck Canada - distributor])

Keppra® will be a limited use benefit for adjunctive therapy in the management of patients with epilepsy not controlled with conventional therapy.

a) For use in combination with other anti-epileptic medication(s) in the treatment of partial seizures in patients who are refactory to adequate trials of three anti-epileptic medications used either as monotherapy or in combination. This product must be prescribed by a Neurologist.

3. Atazanavir sulfate, Capsule, 150mg and 200mg (Reyataz™ - Bristol-Myers Squibb Canada)

Reyataz™ will be a limited use benefit for the treatment of HIV-1 infection in antiretroviral-naïve and antiretroviral treatment-experienced patients.

a) For the management of HIV in patients who failed other protease inhibitor combinations, or for patients who experienced a lack of tolerability to other protease inhibitors.

NEW INDICATIONS ADDED TO EXISTING LIMITED USE BENEFITS

1. Salmeterol xinafoate/fluticasone propionate, Powder for Inhalation, 50mcg & 250mcg and 50mcg & 500mcg (Advair Diskus® - GlaxoSmithKline)

a) For the treatment of moderate** to severe** COPD, if a patient continues to be symptomatic after an adequate trial (2-4 months) of ipatroprium at a dose of 4 puffs four times daily and short-acting beta 2-agonists (indicating poor control).

**Canadian Thoracic Society COPD classification

By Symptom/Disability:

Moderate: shortness of breath from COPD causing the patient to stop after walking approximately 100 meters (or after a few minutes) on the level.

Severe: shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

2. Imatinib mesylate, Capsule, 100mg (Gleevec™ - Novartis)

The following new indication will be added to the existing criteria:

a) For newly diagnosed adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (CML)

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

1. Telithromycin, Tablet, 400mg (Ketek™ - Aventis Pharma Inc.)

2. Peginterferon alfa-2a, Solution, 180mcg/mL and 180mcg/ 0.5mL (Pegasys® - Hoffman-LaRoche Limited)

3. Gefitinib, Tablet, 250mg (Iressa - AstraZeneca Canada Inc.)

4. Mirtazapine, Rapid Dissolving Tablet, 15mg, 30mg and 45mg (Remeron RD - Organon Canada Ltd.)

5. Norelgestromin/ethinyl estradiol, Transdermal Patch, 6mg & 0.60mg (Evra - Janssen-Ortho Inc.)

NIHB DEFERRED DECISION ON LISTING

1. Enfuvirtide, Powder for Solution, 108mg/Vial (Fuzeon® - Hoffman La Roche Limited)

2. Etanercept, Injection, 25mg/mL (Enbrel® -New Indications)

3. Methylphenidate hydrochloride, Extended-Release Tablet, 18mg, 36mg and 54mg (Concerta®)

4. Perindopril erbumine/indapamide, Tablet, 2mg & 0.625mg (Preterax®)

CHANGES IN BENEFIT STATUS

(Effective January 1, 2005)

Carvedilol, Tablet, 3.125mg, 6.25mg, 12.5mg and 25mg (Coreg® - GlaxoSmithKline and Generics) will change status from an exception to a limited use benefit, effective January 1, 2005. The criteria for use will be as follows:

a) For patients with systolic heart failure of ischemic or non-ischemic origin, with or without digoxin, PLUS

b) Concurrent treatment with diuretics and angiotension converting enzyme inhibitors or angiotension receptor blockers, unless contraindicated.

BENEFITS DELISTED FROM THE NIHB DRUG BENEFIT LIST:

As a result of Merck Frosst Canada & Co. announcement of their voluntary worldwide withdrawal of Vioxx ® (rofecoxib) from the market, Vioxx® has been delisted as a benefit under the NIHB Program, effective September 30th, 2004.

EXPANDING MAXIMUM ALLOWABLE QUANTITIES FOR NARCOTIC COMBINATION PRODUCTS

Currently, the NIHB Program has a quantity limitation for products containing codeine 30mg in combination with either acetaminophen or acetylsalicylic acid and with or without caffeine. A total of 1080 tablets is allowed in a 90-day period. All paid claims for any codeine 30mg combination analgesic product are counted towards the maximum allowable quantity.

Utilization patterns of other narcotic products were closely monitored following implementation of maximum allowable quantities for the codeine-containing analgesics. Effective January 1, 2005, the NIHB Program will be expanding the maximum allowable quantities to include other narcotic combination products containing codeine 15mg and 60mg in combination with either acetaminophen or acetylsalicylic acid and with or without caffeine. As well, maximum allowable quantities will be applied to

products containing oxycodone with either acetaminophen or acetylsalicylic acid. A total of 1200 tablets will be allowed in a 100-day period. All paid claims for these narcotic combination products will be counted towards the maximum allowable quantity.

EMERGENCY SUPPLY POLICY

Recent analysis of NIHB claims has shown what appears to be systematic use of the Program's emergency supply policy. Providers are therefore reminded that when a drug requiring prior approval is needed on an emergency basis, and access to the NIHB Drug Exception Centre is not possible (e.g. statutory holidays and after hours of operation only), a pharmacist may dispense an initial course of treatment (maximum of four days supply). It is important that the pharmacist contact the NIHB Drug Exception Centre as soon as possible for an approval to be backdated to cover the emergency supply. This approval number must be included when submitting the four day emergency supply claim. Additional dispensing of the balance of the prescription must follow the usual prior approval process.

If a prior approval is granted, the pharmacist is provided with a prior approval number and the details of the approved benefit by fax. The prior approval number must be included on any subsequent claim submitted for the requested approved drug benefit.

Claims submitted to the Program as emergency supply within the hours of operation of the NIHB Drug Exception Centre will be subject to audit.

NIHB DRUG USE EVALUATION ADVISORY COMMITTEE

In December 2003, the NIHB Program created a Drug Use Evaluation Advisory Committee (DUEAC). The purpose of the DUEAC is to provide recommendations to the NIHB Program to promote improvement in the health outcomes of First Nations and Inuit clients through effective use of pharmaceuticals. The Drug Use Evaluation (DUE) Program will be developed within the context of First Nations and Inuit holistic health views encompassing the determinants of health.

The DUE Program will aim to foster relationships and engage First Nations and Inuit communities and health care professionals in optimizing drug use.

Specific drug utilization reviews are recommended to the NIHB Program and the results subsequently interpreted by the DUEAC. The Committee is an independent advisory body of licensed health care professionals - experts in drug use evaluation, Aboriginal health issues and drug utilization. Criteria used by the Committee will be consistent with standard, accepted references, sources of drug information or peer-reviewed literature. All analytical work will be conducted on an anonymized dataset to ensure individual client's privacy is respected.

The majority of DUE Advisory Committee efforts will be focused on initiatives that change broad practices, and thus impact health outcomes of the entire client population. The NIHB Program will introduce a new DUE Bulletin in the near future to provide information to prescribers and pharmacy providers on the findings and recommendations of the DUEAC. The first of these Bulletins will highlight the results of an analysis of diabetic claimants within the NIHB Program.

IMPORTANT DRUG SAFETY INFORMATION

The following is taken from the Therapeutic Products Directorate Web site:

Health Canada has recently issued warnings for SSRIs and other recent anti-depressants regarding the potential for behavioural and emotional changes, including risk of self harm.

For further information and for other Health Canada Advisories, please visit the Health Canada Web site at:

www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_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

NOVEMBER 2004 REPORT OF THE AUDITOR GENERAL OF CANADA TO THE HOUSE OF COMMONS

Chapter 4 – Management of Federal Drug Benefit Programs.

Drug benefit programs are one of the fastest growing areas of federal spending on health. Between 2000-01 and 2002-03, spending grew from $350 million to $438 million, a 25 percent increase in just two years. The chapter looks at the drug benefit programs of Health Canada (benefits for First Nations and Inuit), Veterans Affairs Canada (veterans), National Defence (Canadian Forces members), the Royal Canadian Mounted Police (force members), Citizenship and Immigration Canada (certain designated classes of migrants), and Correctional Service Canada (inmates of federal penitentiaries and some former inmates on parole). The NIHB Program will be responding to the findings of the audit when they are published.

For additional information please visit the Office of the Auditor General of Canada Web Site at:

www.oag-bvg.gc.ca