Health Canada Santé Canada

Summer 2015

Non-Insured Health Benefits

First Nations and Inuit Health Branch

Updates to the Drug Benefit List

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 been found to be effective 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 the 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 NIHB Drugs and Therapeutics Advisory Committee (DTAC). 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" from the attending licensed practitioner. These requests are reviewed on a case by case basis.

Exclusion: Certain drug therapies for particular conditions fall outside the NIHB Program's mandate and will not be provided as benefits (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 DTAC 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 does not apply to excluded drugs.

ADDITIONS TO THE DRUG BENEFIT LIST

OPEN BENEFITS

Single-Source Drug Products

DIN	MFR	BRAND NAME	Effective Date
02221810	VAE	LOPROX 1% LOTION	07-04-2015
02221802	VAE	LOPROX 1% CREAM	07-04-2015
02237514	BAY	CIPRO 10G/100ML ORAL LIQUID	04-06-2015
02426501	KEG	PREZCOBIX 150MG/800MG TABLET	27-05-2015
02424924	TEP	DIVIGEL 0.25MG TRANSDERMAL GEL	06-05-2015
80042704	PFI	[ST] CENTRUM PRENATAL DHA	04-05-2015
01919466	PFI	[ST] CYTOMEL 25MCG TABLET	27-05-2015
01919458	PFI	[ST] CYTOMEL 5MCG TABLET	27-05-2015
02352699	PED	RHINARIS NASAL GEL	14-07-2015
02417456	WAC	LOLO TABLET	26-03-2015
80045822	PFI	[ST] CENTRUM PRENATAL MULTIVITAMINS	04-05-2015
02429489	LEO	INNOHEP 16000IU/0.8ML INJECTION	19-03-2015
02429462	LEO	INNOHEP 8000IU/0.4ML INJECTION	19-03-2015

DIN (Drug Identification Number)
MFR (Manufacturer)
ST (Short-Term Dispensing Policy Drug)

Canada

Multi-Source Drug Products

DIN	MFR	BRAND NAME	Effective Date
02433044	PMS	[ST] ASA 81MG TABLET	19-06-2015
02427206	VTH	[ST] JAMP-ASA 81 MG EC TABLET	09-07-2015
02429950	MAN	[ST] M-ASA 80MG TABLET	08-04-2015
02392143	BMI	[ST] BIO-AMLODIPINE 10MG TABLET	13-03-2015
02392127	BMI	[ST] BIO-AMLODIPINE 2.5MG TABLET	13-03-2015
02392135	BMI	[ST] BIO-AMLODIPINE 5MG TABLET	13-03-2015
02392488	BMI	BIO-ANASTROZOLE 1MG TABLET	13-03-2015
02392186	BMI	[ST] BIO-ATENOLOL 100MG TABLET	13-03-2015
02392194	BMI	[ST] BIO-ATENOLOL 25MG TABLET	13-03-2015
02392178	BMI	[ST] BIO-ATENOLOL 50MG TABLET	13-03-2015
02274574	PFI	GD-AZITHROMYCIN 200MG/5ML ORAL LIQUID	15-04-2015
02274531	PFI	GD-AZITHROMYCIN 250MG TABLET	15-04-2015
02211076	APX	APO-BUSPIRONE 10MG TABLET	21-04-2015
02230942	PMS	PMS-BUSPIRONE 10MG TABLET	21-04-2015
02231492	TEP	TEVA-BUSPIRONE 10MG TABLET	21-04-2015
80054754	MAN	[ST] M-CAL 100MG/5ML LIQUID	08-04-2015
80055526	MAN	[ST] M-CAL 500MG TABLET	08-04-2015
80027787	JAP	[ST] JAMP-CALCIUM+VIT D CHEW TABLET	06-03-2015
80050701	MAN	[ST] M CAL D 1000 TABLET	08-04-2015
80029083	JAP	[ST] JAMP CALCIUM VIT D TABLET	06-03-2015
80049201	MAN	[ST] M CITRATE D 1000 ORAL LIQUID	05-05-2015
80054755	MAN	[ST] M-CAL D 500MG/400IU LIQUID	08-04-2015
02403196	ATP	ACT CLARITHROMYCIN XL 500MG TABLET	01-04-2015
02425017	RBY	RAN-CYPROTERONE/ETHINYL ESTRAD	02-06-2015
02341689	PFI	GD-DICLOFENAC/MISOPROSTOL 50	28-04-2015
02341697	PFI	GD-DICLOFENAC/MISOPROSTOL 75	31-03-2015
02429039	SIV	ESCITALOPRAM 10MG TABLET	13-03-2015
02429047	SIV	ESCITALOPRAM 20MG TABLET	13-03-2015
02432471	JAP	JAMP-FLUCONAZOLE 150MG CAPSULE	02-06-2015
02433702	PHA	PRIVA-FLUCONAZOLE 150MG CAPSULE	19-03-2015
02255510	RIV	RIVA-FLUCONAZOLE 150MG CAPSULE	05-03-2015
02400391	ACP	ACCEL-FLUOXETINE 10MG CAPSULE	14-04-2015
02400405	ACP	ACCEL-FLUOXETINE 20MG CAPSULE	14-04-2015
02429764	ATP	[ST] ACT-GLICLAZIDE MR 30MG TABLET	05-05-2015
02407124	APX	[ST] APO-GLICLAZIDE MR 60MG TABLET	05-05-2015
02354799	PED	CHILDREN'S EUROPROFEN 100MG/5	01-04-2015
02414414	AUR	AURO-LAMIVU./ZIDOVU. 150/300	09-07-2015
02392496	BMI	BIO-LETROZOLE 2.5MG TABLET	11-03-2015
02427745	JAP	JAMPOCAINE VISCOUS 2%	17-04-2015
02228351	PMS	PMS-LOPERAMIDE 2MG CAPSULE	21-04-2015
02430487	AUR	AURO-MODAFINIL 100MG TABLET	15-04-2015
02403587	APX	APO-MOMETASONE 50MCG NASAL SPRAY	20-05-2015
02421631	PDL	[ST] NIFEDIPINE ER 30MG TABLET	09-07-2015
02421658	PDL	[ST] NIFEDIPINE ER 60MG TABLET	09-07-2015
02433443	JAP	JAMP-NYSTATIN ORAL SUSPENSION	05-05-2015
02436973	MIN	MINT-OLANZAPINE ODT 10MG TABLET	03-07-2015
02436981	MIN	MINT-OLANZAPINE ODT 15MG TABLET	03-07-2015
02436965	MIN	MINT-OLANZAPINE ODT 5MG TABLET	03-07-2015
02422727	MIN	MINT-OLOPATADINE 0.1% OPHTHALMIC SOLUTION	18-06-2015
02417839	NPH	NAT-ONDANSETRON 4MG TABLET	14-04-2015
02417847	NPH	NAT-ONDANSETRON 8MG TABLET	14-04-2015
80053887	PDL	[ST] PRO-K 20 TABLET	09-03-2015
80011428	MAN	[ST] M-K EFFERLYTE TABLET	05-05-2015
02400359	ACP	ACCEL-QUETIAPINE 100MG TABLET	14-04-2015

DIN	MFR	BRAND NAME	Effective Date
02400375	ACP	ACCEL-QUETIAPINE 200MG TABLET	14-04-2015
02400340	ACP	ACCEL-QUETIAPINE 25MG TABLET	14-04-2015
02400383	ACP	ACCEL-QUETIAPINE 300MG TABLET	14-04-2015
80055641	MAN	[ST] M-SENNOSIDES 12MG TABLET	14-04-2015
80019511	BMI	[ST] BIO-SENNOSIDES 8.6MG TABLET	19-03-2015
80054498	MAN	[ST] M SENNOSIDES 8.6MG TABLET	14-04-2015
02432897	PMS	[ST] TELMISARTAN 40MG TABLET	18-03-2015
02432900	PMS	[ST] TELMISARTAN 80MG TABLET	18-03-2015
02433214	PMS	[ST] TELMISARTAN-HCTZ 80/12.5MG TABLET	02-06-2015
02433222	PMS	[ST] TELMISARTAN-HCTZ 80/25MG TABLET	02-06-2015
80054205	MAN	[ST] M-B1 100MG TABLET	08-04-2015
80054199	MAN	[ST] M-B1 50MG TABLET	08-04-2015
02435357	ACP	ACCEL-TOPIRAMATE 200MG TABLET	17-04-2015
02435330	ACP	ACCEL-TOPIRAMATE 25MG TABLET	17-04-2015
02409097	PFI	GD-TRANEXAMIC ACID 500MG TABLET	23-06-2015
02299313	DOM	DOM-VENLAFAXINE XR 150MG CAPSULE	09-03-2015
02299291	DOM	DOM-VENLAFAXINE XR 37.5MG CAPSULE	09-03-2015
80054130	JAP	[ST] JAMP-VITAMIN A 10000IU CAPSULE	05-05-2015
80055741	MAN	[ST] M-B12 1000MCG TABLET	09-07-2015
80055743	MAN	[ST] M-B12 250MCG TABLET	09-07-2015
80056458	MAN	[ST] M-B6 25MG TABLET	05-05-2015
80055204	MAN	[ST] M-D 1000IU CAPSULE	15-04-2015
80055196	MAN	[ST] M-D 400IU CAPSULE	14-04-2015
80051562	RIV	[ST] RIVA-D 1000IU CAPSULE	09-03-2015
80043412	BMI	[ST] VITAMIN D 1000IU CAPSULE	19-03-2015
02337452	HSI	DIAPER RASH CREAM	20-07-2015

NEW LIMITED USE BENEFITS

DIN	MFR	BRAND NAME	Effective Date
02362201	RIV	[ST] ACETAMIN. BLASON SHIELD 500MG	16-03-2015
02362198	RIV	[ST] ACETAMINOPHENE 325MG CAPLET	16-03-2015
02362228	RIV	[ST] ACETAMINOPHENE 500MG CAPLET	16-03-2015

Limited use benefit (prior approval is not required).

For safety reasons NIHB has implemented a dose limit on acetaminophen. The limit accumulates against the amount of acetaminophen claimed to the program from plain acetaminophen and/or acetaminophen in combination with opioids such as codeine (i.e. Tylenol® #3) or oxycodone (i.e. Percocet®). A total of 360 grams of acetaminophen is permitted in a 100-day period, for a total daily dose of 3600mg/day.

96899972	TRU	RESPICHAMBER VHC W MOUTHPIECE	08-07-2015

Limited use benefit with quantity and frequency limits (prior approval is not required).

Coverage is granted for 1 spacer device every 12 months.

DIN	MFR	BRAND NAME	Effective Date
02401126	ACP	[ST] ACCEL-ALENDRONATE 10MG TABLET	01-04-2015
02401118	ACP	[ST] ACCEL-ALENDRONATE 5MG TABLET	01-04-2015
02401134	ACP	[ST] ACCEL-ALENDRONATE 70MG TABLET	01-04-2015
02384701	RBY	[ST] RAN-ALENDRONATE 10MG TABLET	13-03-2015

Limited use benefit (prior approval required).

For the treatment of:
•Paget's Disease OR
•Osteoporosis in patients who are 60 years of age or over OR
•Osteoporosis in patients under 60 who have documented hip, vertebral or other fractures OR
•Osteoporosis in patients under 60 with no evidence of fracture but who have a high (>20%) 10-year fracture risk OR
•Osteoporosis or risk of osteoporosis in patients under 60 who have been, or who will be, on systemic corticosteroid therapy equivalent to a dose of prednisone ≥ 7.5mg per day for ≥3 months.

02404907	RIV	RIVA-ALPRAZOLAM 2MG TABLET	03-07-2015

Limited use benefit (prior approval is not required).

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented a benzodiazepine dose limit of 40 mg diazepam equivalents per day. This limit will be calculated based on the total dose of all benzodiazepines a client is receiving from NIHB within a 100-day period (i.e. 4 000 diazepam equivalents over 100 days). According to the product monograph for diazepam, the recommended usual adult dosage is up to 40 mg per day.

09857525	BNM	GE200 GLUCOSE TEST STRIPS (ON)	12-06-2015
97799373	BNM	GE200 GLUCOSE TEST STRIPS 100	12-06-2015
97799355	SKY	SURETEST TEST STRIPS	12-06-2015
09857522	SKY	SURETEST TEST STRIPS (ON)	12-06-2015

Limited use benefit (prior approval not required).

The number of test strips that will be covered by the NIHB Program will depend on the client's medical treatment:

•Clients managing diabetes with insulin will be allowed 500 test strips per 100 days. A client can test up to five times per day.
•Clients managing diabetes with diabetes medication with a high risk of causing low blood sugar will be allowed 400 test strips per 365 days. A client can test once daily.
•Clients managing diabetes with diabetes medication with a low risk of causing low blood sugar will be allowed 200 test strips per 365 days. A client can test three to four times per week.
•Clients managing diabetes with diet/lifestyle therapy only (no insulin or diabetes medications) will be allowed 200 test strips per 365 days. A client can test three to four times per week.

80020974	OPS	[ST] OPUS CAL-D 400 TABLET	29-04-2015

Limited use benefit (prior approval is not required).

ASA 80 mg tablets are a benefit to clients age 21 years and under to allow access for use in pediatric conditions (e.g. Kawasaki Syndrome).

02435632	ACP	ACCEL-CELECOXIB 100MG CAPSULE	01-04-2015
02435640	ACP	ACCEL-CELECOXIB 200MG CAPSULE	01-04-2015
02436299	SAN	CELECOXIB 100MG CAPSULE	09-03-2015
02436302	SAN	CELECOXIB 200MG CAPSULE	09-03-2015

Limited use benefit (prior approval required).

For patients who have:
•a history of serious gastrointestinal complications (e.g. ulcer, bleeding, perforation);
OR
•multiple (at least tw) risk factors for serious gastrointestinal complications (e.g. age >60, concurrent use of ASA, SSRIs, corticosteroids, anticoagulants or antiplatelet agents).

DIN	MFR	BRAND NAME	Effective Date
02412861	BMI	BIO-DONEPEZIL 10MG TABLET	11-03-2015
02412853	BMI	BIO-DONEPEZIL 5MG TABLET	11-03-2015

Limited use benefit (prior approval required).

Initial six month coverage for cholinesterase inhibitors:
•Diagnosis of mild to moderate Alzheimer's disease; AND
•Mini Mental State Exam (MMSE) score of 10-26, established within the last 60 days; AND
•Global Deterioration Scale (GDS) score between 4 to 6, established within the last 60 days
•Continued coverage beyond 6 months will be based on improvement or stabilization of cognition, function or behaviour.

Criteria for coverage at every six month interval:
•Diagnosis is still mild to moderate Alzheimer's disease; AND
•MMSE score > 10; AND
•GDS score between 4 to 6; AND
•Improvement or stabilization in at least one of the following domains (please indicate improved, worsened, or no change)
1.Memory, reasoning and perception (e.g., names, tasks, MMSE)
2.Instrumental activities of daily living (IADLs: e.g., telephone, shopping, meal preparation)
3.Basic activities of daily living (e.g., bathing, dressing, hygiene, toileting)
4.Neuropsychiatric symptoms (e.g., agitation, delusions, hallucination, apathy)

02269007	HLR	TARCEVA 25MG TABLET	22-05-2015
02377705	TEP	TEVA-ERLOTINIB 100MG TABLET	16-04-2015
02377713	TEP	TEVA-ERLOTINIB 150MG TABLET	16-04-2015
02377691	TEP	TEVA-ERLOTINIB 25MG TABLET	26-05-2015

Limited use benefit (prior approval required).

Treatment of non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen, and whose EGFR expression status is positive or unknown.

02380021	PFI	[ST] TOVIAZ 4MG TABLET	27-05-2015
02380048	PFI	[ST] TOVIAZ 8MG TABLET	27-05-2015

Limited use benefit (prior approval required).

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.

02418282	NOV	ULTIBRO BREEZHALER 50/110MCG	14-04-2015

Limited use benefit (prior approval required).

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who:
•have moderate to severe COPD, defined as <60% FEV1, FEV1/FVC<0.7 and MRC 3 to 5; AND
•who had an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

02429810	SIV	LORAZEPAM 1MG TABLET	02-06-2015
02429829	SIV	LORAZEPAM 2MG TABLET	02-06-2015

Limited use benefit (prior approval is not required).

To promote safe, therapeutically effective and efficient use of drug therapy NIHB has implemented a benzodiazepine dose limit of 40 mg diazepam equivalents per day. This limit will be calculated based on the total dose of all benzodiazepines a client is receiving from NIHB within a 100-day period (i.e. 4 000 diazepam equivalents over 100 days). According to the product monograph for diazepam, the recommended usual adult dosage is up to 40 mg per day.

DIN	MFR	BRAND NAME	Effective Date
02387786	SPC	LATUDA 120MG TABLET	01-04-2015
02387751	SPC	LATUDA 40MG TABLET	01-04-2015
02387778	SPC	LATUDA 80MG TABLET	01-04-2015

Limited use benefit (prior approval required).

For the treatment of schizophrenia and schizoaffective disorders in patients who have
•intolerance or lack of response to an adequate trial of another antipsychotic agent; OR
•a contraindication to another antipsychotic agent

02422867	AUR	AURO-MONTELUKAST 4MG CHEWABLE TABLET	15-04-2015
02422875	AUR	AURO-MONTELUKAST 5MG CHEWABLE TABLET	15-04-2015

Limited use benefit (prior approval required).

For treatment of:
•asthma when used in patients on concurrent steroid therapy.
•asthma patients not well controlled with or intolerant to inhaled corticosteroids.

02437945	PMS	[ST] PANTOPRAZOLE 40MG TABLET	03-07-2015

Limited use benefit (prior approval not required).

Coverage will be limited to 400 tablets/capsules every 180 days.

02439573	MIN	MINT-RIZATRIPTAN ODT 5MG TABLET	03-07-2015
02436612	NPH	NAT-RIZATRIPTAN ODT 10MG TABLET	18-03-2015
02436604	NPH	NAT-RIZATRIPTAN ODT 5MG TABLET	18-03-2015

Limited use benefit (prior approval is not required).

A total of 12 tablets (or injections) are permitted in a 30-day period.

02432226	GIL	HARVONI 400MG/90MG TABLET	13-04-2015

Limited use benefit (prior approval required).

For the treatment of chronic hepatitis C virus (HCV) genotype1 infection in adults with a liver fibrosis stage ≥ F2 (Metavir score or equivalent).

Criteria & Duration
Treatment-naïve patients with no cirrhosis, viral load < 6 million IU/mL -8 weeks*
Treatment-naïve patients with no cirrhosis, viral load ≥ 6 million IU/mL -12 weeks
Treatment-naïve patients with compensated cirhosis - 12 weeks
Treatment-experienced patients with no cirrhosis - 12 weeks
Treatment-experienced patients with compensated cirrhosis 24 weeks

*For this population cohort (treatment naïve, non-cirrhotic, viral load < 6 million IU/mL), evidence has shown that the SVR rates with the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients may be considered for 12 weeks of coverage if they have severe fibrosis/borderline cirrhosis (F3-4) or if they are co-infected with HIV.

Not eligible for coverage:
• Patients currently being treated with another HCV antiviral agent
• Patients who have previously received a treatment course of Harvoni (Re-treatment requests will not be considered).

02408163	ACY	FIBRISTAL 5MG TABLET	25-05-2015

Limited use benefit (prior approval not required).

Coverage will be limited to 90 tablets.

DIN	MFR	BRAND NAME	Effective Date
02418401	GSK	ANORO ELLIPTA 62.5/25MCG INHALER	14-04-2015

Limited use benefit (prior approval required).

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who:
•have moderate to severe COPD, defined as <60% FEV1, FEV1/FVC<0.7 and MRC 3 to 5; AND
•who had an inadequate response to a long-acting bronchodilator (long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

02421534	NPH	NAT-ZOLMITRIPTAN 2.5MG TABLET	13-03-2015

Limited use benefit (prior approval is not required).

A total of 12 tablets (or injections) are permitted in a 30-day period.

CRITERIA CHANGES

LISTING OF BUSPIRONE

Effective April 21, 2015, buspirone oral tablets, 10 mg became an open benefit based on a recommendation from DTAC. The listing status of oral buspirone was changed from non-benefit to open benefit.

CHANGE IN THE LISTING CRITERIA OF ORAL VANCOMYCIN

Effective June 15, 2015, oral vancomycin capsules, 125mg and 250mg became a limited use benefit (LU). This was based on a recommendation from DTAC who recommended that oral vancomycin be listed with the following criteria:

For the treatment of patients diagnosed with symptomatic Clostridium difficile infection who:

•are allergic, resistant or intolerant to metroniazole; OR
•have failed to respond to 4-6 days of oral metronidazole at doses of 500mg three times day; OR
•have severe disese and initial doses are prescribed/recommended by an infectious disease or gastro-intestinal specialist

The maximum approval allowed per treatment four times a day (QID) x 14 days

LISTING OF CYTOMEL

Effective May 27, 2015, Cytomel oral tablets, 5mcg and 25mcg became open benefits on the NIHB DBL.

This change in listing status applied to the following DINs:
•01919458 CYTOMEL 5MCG TABLET
•01919466 CYTOMEL 25MCG TABLET

LISTING OF LOPROX

Effective April 7, 2015, Loprox 1% cream and lotion became open benefits on the NIHB DBL.

This change in listing status applied to the following DINs:
•02221802 LOPROX 1% CREAM
•02221810 LOPROX 1% LOTION