Health Canada Santé Canada

Winter 2017

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)/pan-Canadian Oncology Drug Review (pCODR) processes 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
02430932	VII	TRIUMEQ 600/50/300MG TABLET	08-02-2017
02449277	TRI	ST ASA 81MG TABLET	23-11-2016
02442256	ORM	ST VIDEXTRA 2,000U CAPSULE	05-01-2017
02446561	GSK	ARNUITY ELLIPTA 100MCG/BLD INHALER	17-02-2017
02446588	GSK	ARNUITY ELLIPTA 200MCG/BLD INHALER	17-02-2017
02244290	PAL	METADOL-D 10MG/ML O/L	08-02-2017
02213826	TEP	REVIA 50MG TABLET	05-11-2016
01967878	SCH	CLEAR AWAY PLANTAR WART SYSTEM	30-11-2016
99401033	UNK	SHARPS NESTABLE YELLOW LARGE 22.7L	30-11-2016
01902776	SAO	KAYEXALATE 100%	17-01-2017

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

Canada

Multi-Source Drug Products

DIN	MFR	BRAND NAME	Effective Date
02454513	AUR	AURO-ABACAV/LAMIVUD 600/300MG	11-01-2017
02458381	PMS	PMS-ABACAV/LAMIVUD 600/300MG	27-01-2017
02452324	MAR	MAR-AZITHROMYCIN 250MG TABLET	21-01-2017
02429063	SDZ	VISTITAN 0.03%	11-01-2017
02447851	SAN	ST BUSPIRONE 10MG TABLET	28-11-2016
80025360	JAP	J-CAL-D 400 TABLET	19-12-2016
80065914	RIV	RIVA-CAL D400 TABLET	20-12-2016
02450526	PDL	ST CETIRIZINE 20MG TABLET	23-11-2016
02436914	AUR	AURO-CLINDAMYCIN 300MG CAPSULE	11-01-2017
02454297	ATP	ST ACT ESCITALOPRAM ODT 10MG TABLET	09-01-2017
02454300	ATP	ST ACT ESCITALOPRAM ODT 20MG TABLET	09-01-2017
02398869	MYL	ST INDAYO 0.15MG AND 0.03MG TABLET	06-12-2016
02448424	BMI	ST BIO-FLUOXETINE 10MG CAPSULE	07-11-2016
02448432	BMI	ST BIO-FLUOXETINE 20MG CAPSULE	07-11-2016
02423650	AUR	ST AURO-LOSARTAN-HCTZ 100/12.5MG	28-11-2016
02423669	AUR	ST AURO-LOSARTAN-HCTZ 100/25MG	28-11-2016
02423642	AUR	ST AURO-LOSARTAN-HCTZ 50/12.5MG	28-11-2016
09991474	UNK	NALOXONE NASAL SPRAY	22-12-2016
02444275	APX	APO-NALTREXONE 50MG TABLET	04-11-2016
02448734	AUR	ST AURO-OLANZAPINE ODT 10MG TABLET	30-11-2016
02448742	AUR	ST AURO-OLANZAPINE ODT 15MG TABLET	30-11-2016
02448726	AUR	ST AURO-OLANZAPINE ODT 5MG TABLET	30-11-2016
80033602	JAP	ST JAMP-K EFFERVESCENT 25MMOL TABLET	07-12-2016
02424061	AUR	ST AURO-PRAMIPEXOLE 0.25MG TABLET	30-11-2016
02424118	AUR	ST AURO-PRAMIPEXOLE 1.5MG TABLET	30-11-2016
02424096	AUR	ST AURO-PRAMIPEXOLE 1MG TABLET	30-11-2016
02442582	AUR	ST AURO-ROSUVASTATIN 10MG TABLET	27-01-2017
02442590	AUR	ST AURO-ROSUVASTATIN 20MG TABLET	27-01-2017
02442604	AUR	ST AURO-ROSUVASTATIN 40MG TABLET	27-01-2017
02442574	AUR	ST AURO-ROSUVASTATIN 5MG TABLET	27-01-2017
02453568	AUR	ST AURO-TELMISARTAN 40MG TABLET	11-01-2017
02453576	AUR	ST AURO-TELMISARTAN 80MG TABLET	11-01-2017
02456389	AUR	ST AURO-TELMISARTAN-HCTZ 80/12.5	11-01-2017
02456397	AUR	ST AURO-TELMISARTAN-HCTZ 80/25MG	11-01-2017
02432102	MAR	ST MAR-TOPIRAMATE 100MG TABLET	06-12-2016
02432110	MAR	ST MAR-TOPIRAMATE 200MG TABLET	06-12-2016
02432099	MAR	ST MAR-TOPIRAMATE 25MG TABLET	06-12-2016
02454645	SAN	VALACYCLOVIR 500MG TABLET	06-12-2016
02452855	AUR	ST AURO-VENLAFAXINE XR 150MG CAPSULE	06-12-2016
02452839	AUR	ST AURO-VENLAFAXINE XR 37.5MG CAPSULE	28-11-2016
02452847	AUR	ST AURO-VENLAFAXINE XR 75MG CAPSULE	06-12-2016
02450488	MYL	ST MYLAN-VERAPAMIL SR 180MG TABLET	07-11-2016

NEW LIMITED USE BENEFITS

DIN	MFR	BRAND NAME	Effective Date
02448777	AUR	AURO-ENTECAVIR 0.5MG TABLET	07-11-2016

Limited use benefit (prior approval required).

For the treatment of chronic hepatitis B infection in patients with cirrhosis documented on radiologic or histologic grounds and a HBV DNA concentration above 2000IU/mL.

DIN	MFR	BRAND NAME	Effective Date
02402874	AST	[ST] MYRBETRIQ 25MG TABLET	22-11-2016
02402882	AST	[ST] MYRBETRIQ 50MG TABLET	22-11-2016

Limited Use (prior approval required).

For the symptomatic relief of overactive bladder in patients:
- With symptoms of urinary frequency, urgency or urge incontinence; AND
- Who have failed on or are intolerant to therapy with immediate-release oxybutynin OR solifenacin OR tolterodine ER.

02435470	AZE	[ST] FORXIGA 10MG TABLET	08-02-2017
02435462	AZE	[ST] FORXIGA 5MG TABLET	08-02-2017

Limited use benefit (prior approval required).

For the treatment of patients with type 2 diabetes mellitus who did not achieve glycemic control or who demonstrated intolerance to an adequate trial of metformin AND a sulfonylurea.

02323052	PFI	INSPRA 25MG TABLET	16-12-2016
02323060	PFI	INSPRA 50MG TABLET	16-12-2016

Limited use benefit (prior approval required).

For the treatment of patients with New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction ≤ 35%), as an adjunct to standard therapy.

Patients must be on optimal therapy with an angiotensin-converting-enzyme (ACE) inhibitor or an angiotensin-receptor blocker (ARB), and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

02444186	GSK	BREO ELLIPTA 200/25MCG INHALER	16-12-2016

Limited use benefit (prior approval required).

For the treatment of asthma in patients who are not adequately controlled on medium doses of inhaled corticosteroids (e.g. fluticasone 251-500mcg daily, or the equivalent) as the sole agent and require addition of a long-acting beta agonist. Patients using this combination product must also have access to a short-acting bronchodilator for symptomatic relief.

02438798	GIL	ZYDELIG 100MG TABLET	30-01-2017
02438801	GIL	ZYDELIG 150MG TABLET	30-01-2017

Limited use benefit (prior approval required).

Criteria for initial six month coverage of Zydelig:
- For the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) in combination with rituximab. Treatment should continue until unacceptable toxicity or disease progression.

Criteria for assessment every six months:
- There is no objective evidence of disease progression.

97799342	UNO	INSET 30 INFUSION SETS, 43"	13-01-2017

Limited use benefit (prior approval required).

Patient has type 1 diabetes; AND The insulin pump is prescribed by an endocrinologist or a specialist prescriber with experience in the use of insulin pumps in children, adolescent and/or adults.

00970328	PRN	FLEXI-T +300 IUD	06-02-2017
00970336	PRN	FLEXI-T +380 IUD	06-02-2017

Limited use benefit (prior approval not required).

Coverage is granted for 1 device every 12 months.

DIN	MFR	BRAND NAME	Effective Date
02443066	BOE	OFEV 100MG CAPSULE	16-12-2016
02443074	BOE	OFEV 150MG CAPSULE	16-12-2016

Limited use benefit (prior approval required).

Initial Request - Coverage is provided for a period of 7 months (6 months plus a 4 weeks allowance for repeat pulmonary function tests).

For the treatment of adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF) who meet the following criteria:
- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months; AND
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded; AND
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted; AND
- Patient is under the care of a physician with experience in IPF.

Renewal at 6 months - Coverage is provided for a period of 6 months.
- Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Subsequent Renewals at 12 months and thereafter - Coverage is provided for a period of 12 months.
- Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

02393751	HLR	ESBRIET 267MG CAPSULE	23-12-2016

Limited use benefit (prior approval required).

Initial Request - Coverage is provided for a period of 7 months (6 months plus a 4 weeks allowance for repeat pulmonary function tests).

For the treatment of adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF) who meet the following criteria:
- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months; AND
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded; AND
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted; AND
- Patient is under the care of a physician with experience in IPF.

Renewal at 6 months - Coverage is provided for a period of 6 months.
- Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Subsequent Renewals at 12 months and thereafter - Coverage is provided for a period of 12 months.
- Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

02410702	SLX	ZAXINE 550MG TABLET	09-11-2016

Limited use benefit (prior approval required).

For reducing the risk of overt hepatic encephalopathy (HE) recurrence in patients:
- Who are unable to achieve adequate control of HE recurrence with a maximal tolerated dose of lactulose alone; AND
- When used in combination with a maximal tolerated dose of lactulose.

DIN	MFR	BRAND NAME	Effective Date
02441144	AUR	AURO-RIZATRIPTAN 10MG TABLET	17-01-2017

Limited use benefit (prior approval not required).

A total of 12 tablets are permitted in a 30-day period.

00330191	JAM	[ST] VITAMIN E 800IU NAT SOURCE CAPSULE	19-01-2017

Limited use benefit (prior approval required).

For use in malabsorption.

CRITERIA CHANGES

CHANGE IN COVERAGE OF APTIVUS

Effective December 6, 2016, Aptivus became an open benefit

The following DINs were affected:
02273322 APTIVUS 250MG CAPSULE

CHANGE IN COVERAGE OF CELSENTRI

Effective December 6, 2016, Celsentri became an open benefit

The following DINs were affected:
02299844 CELSENTRI 150MG TABLET

CHANGE IN COVERAGE OF INTELENCE

Effective December 6, 2016, Intelence became an open benefit

The following DINs were affected:
02306778 INTELENCE 100MG TABLET
02375931 INTELENCE 200MG TABLET

CHANGE IN COVERAGE OF ISENTRESS

Effective December 6, 2016, Isentress became an open benefit

The following DINs were affected:
02301881 ISENTRESS 400MG TABLET

CHANGE IN COVERAGE OF BISMUTH IN TABLETS AND SUSPENSION (PEPTO-BISMOL)

Effective January 3, 2017, bismuth products (Pepto-Bismol) in tablet and suspension form will have a frequency limit. The maximum amount will be 8 tablets per day for 14 days or 120mL per day of the liquid for 14 days. The NIHB Drugs and Therapeutics Advisory Committee recommended the change in listing status following the review of clinical evidence for bismuth. Evidence of efficacy was only found for the treatment of H. pylori infection for up to 14 days.

CHANGE IN COVERAGE OF ZELDOX

Effective January 20, 2017, Zeldox became an open benefit.

The following DINs were affected:
02298597 ZELDOX 20MG CAPSULE
02298600 ZELDOX 40MG CAPSULE
02298619 ZELDOX 60MG CAPSULE
02298627 ZELDOX 80MG CAPSULE

CHANGE IN COVERAGE OF ABILIFY MAINTENA

Effective January 27, 2017, Abilify Maintena became an open benefit.

The following DINs were affected:
02420864 ABILIFY MAINTENA 300MG INJECTION
02420872 ABILIFY MAINTENA 400MG INJECTION