Health Canada Santé Canada

Summer 2013

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	ITEM NAME	Effective Date
09857368	ALL	LUMIGAN RC 0.01% OPHTHALMIC 5ML (ON)	21-05-2013
02241091	DCM	MAGIC BULLET	29-05-2013
02393050	KEG	PREZISTA 800MG TABLET	28-05-2013
00013609	HOR	GRAVOL ADULT SUPPOSITORY 100MG	02-04-2013
02357305	VTH	[ST] STOOL SOFTENER 100MG CAPSULE	01-04-2013
02382059	SAC	ALLERJECT 0.15MG AUTOINJECTOR	28-05-2013
02382067	SAC	ALLERJECT 0.3MG AUTOINJECTOR	28-05-2013
02391449	LUK	CIPRALEX MELTZ 10MG TABLET	01-04-2013
02391457	LUK	CIPRALEX MELTZ 20MG TABLET	01-04-2013
02263238	LUK	CIPRALEX 10MG TABLET	08-04-2013
02263254	LUK	CIPRALEX 20MG TABLET	08-04-2013
97799431	JAJ	ONE TOUCH DELICA 30G LANCET	13-03-2013
97799501	JAJ	ONETOUCH DELICA 33G LANCET	13-03-2013

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

Canada

DIN	MFR	ITEM NAME	Effective Date
02389983	TAK	ONDISSOLVE ODF 4MG/CM FILM	14-03-2013
02389991	TAK	ONDISSOLVE ODF 8MG/CM FILM	13-03-2013
97799404	AUC	CLICKFINE PEN NEEDLE 31G 4.5MM	28-05-2013
97799405	AUC	CLICKFINE PEN NEEDLE 31G 6MM	29-05-2013
97799406	AUC	CLICKFINE PEN NEEDLE 31G 8MM	28-05-2013
97799441	HOD	LIFE BRAND PEN NEEDLE 31G 8MM	28-05-2013
97799425	BTD	BD 0.3ML SYR WITH U/F 6MM NEEDLE	28-05-2013
00266507	ODN	ADASEPT LIQUID 0.5%	01-02-2013

Multi-Source Drug Products

DIN	MFR	ITEM NAME	Effective Date
02402769	APX	[ST] APO-ALLOPURINOL 100MG TABLET	22-05-2013
02402777	APX	[ST] APO-ALLOPURINOL 200MG TABLET	22-05-2013
02402785	APX	[ST] APO-ALLOPURINOL 300MG TABLET	22-05-2013
02396327	MAR	[ST] MAR-ALLOPURINOL 100MG TABLET	04-04-2013
02396335	MAR	[ST] MAR-ALLOPURINOL 200MG TABLET	04-04-2013
02396343	MAR	[ST] MAR-ALLOPURINOL 300MG TABLET	04-04-2013
02404222	PMS	[ST] PMS-AMLODIP-ATORVAST 5/10MG TABLET	17-04-2013
02404230	PMS	[ST] PMS-AMLODIP-ATORVAST 5/20MG TABLET	17-04-2013
02404249	PMS	[ST] PMS-AMLODIPINE-ATORVAS 10/10MG TABLET	17-04-2013
02404257	PMS	[ST] PMS-AMLODIPINE-ATORVAS 10/20MG TABLET	17-04-2013
02401495	SIV	AMOXICILLIN 250MG CAPSULE	03-06-2013
02401541	SIV	AMOXICILLIN 250MG/5ML GRANULE	03-06-2013
02401509	SIV	AMOXICILLIN 500MG CAPSULE	03-06-2013
02392259	RIV	RIVA-ANASTROZOLE 1MG TABLET	09-04-2013
02325985	ACC	BICALUTAMIDE 50MG TABLET	11-04-2013
80003658	WNP	[ST] CALCIUM 500MG TABLET	06-06-2013
02399105	APX	[ST] APO-CANDESARTAN 32MG TABLET	14-03-2013
02395568	TEP	[ST] TEVA-CANDESARTAN/HCTZ 32/12.5 TABLET	05-06-2013
02395576	TEP	[ST] TEVA-CANDESARTAN/HCTZ 32/25MG TABLET	05-06-2013
02395541	TEP	[ST] TEVA CANDESARTAN/HCTZ 16/12.5M TABLET	05-06-2013
02400529	SAN	CLINDAMYCIN 150MG CAPSULE	05-06-2013
02400537	SAN	CLINDAMYCIN 300MG CAPSULE	05-06-2013
02402181	PMS	PMS-COLCHICINE 0.6MG TABLET	14-03-2013
02395797	RIV	RIVA-CYPROTERONE 50MG TABLET	09-04-2013
02396491	FAM	FREYA 21 TABLET	31-05-2013
02396610	FAM	FREYA 28 TABLET	31-05-2013
02400421	SAN	[ST] DILTIAZEM CD 120MG CAPSULE	05-06-2013
02400448	SAN	[ST] DILTIAZEM CD 180MG CAPSULE	05-06-2013
02400456	SAN	[ST] DILTIAZEM CD 240MG CAPSULE	05-06-2013
02400464	SAN	[ST] DILTIAZEM CD 300MG CAPSULE	05-06-2013
02400499	SAN	DIVALPROEX 125MG TABLET	05-06-2013
02400502	SAN	DIVALPROEX 250MG TABLET	05-06-2013
02400510	SAN	DIVALPROEX 500MG TABLET	05-06-2013
02400677	SAN	[ST] ENALAPRIL 10MG TABLET	05-06-2013
02400650	SAN	[ST] ENALAPRIL 2.5MG TABLET	05-06-2013
02400685	SAN	[ST] ENALAPRIL 20MG TABLET	05-06-2013
02400669	SAN	[ST] ENALAPRIL 5MG TABLET	05-06-2013
02390701	SDZ	[ST] SANDOZ FENOFIBRATE E 145MG TABLET	01-02-2013
02390698	SDZ	[ST] SANDOZ FENOFIBRATE E 48MG TABLET	18-04-2013
80029822	JAP	JAMP FERROUS FUMARATE SUSPENSION	14-06-2013
02400235	SDZ	[ST] SANDOZ FLUVASTATIN 20MG CAPSULE	06-06-2013
02400243	SDZ	[ST] SANDOZ FLUVASTATIN 40MG CAPSULE	06-06-2013
80029765	JAP	JAMP GLYCERIN 2100MG SUSPENSION	14-06-2013
02303094	SDZ	HEPARIN SODIUM 10000U/ML INJECTION	26-06-2013
02387646	APX	[ST] APO-IRBESARTAN/HCTZ 150/12.5MG TABLET	08-03-2013

DIN	MFR	ITEM NAME	Effective Date
02387654	APX	[ST] APO-IRBESARTAN/HCTZ 300/12.5MG TABLET	08-03-2013
02387662	APX	[ST] APO-IRBESARTAN/HCTZ 300/25MG TABLET	08-03-2013
02392992	MIN	[ST] MINT-IRBESARTAN/HCTZ 150/12.5 TABLET	22-05-2013
02393018	MIN	[ST] MINT-IRBESARTAN/HCTZ 300/12.5 TABLET	22-05-2013
02393026	MIN	[ST] MINT-IRBESARTAN/HCTZ 300/25 TABLET	22-05-2013
02367335	SDZ	SANDOZ LATANOPROST 50MCG OPHTHALMIC SOLUTION	11-06-2013
02343657	TEP	[ST] TEVA-LETROZOLE 2.5MG TABLET	05-06-2013
02389665	MIN	[ST] MINT-LOSARTAN/HCTZ 100/12.5MG TABLET	22-05-2013
02389657	MIN	[ST] MINT-LOSARTAN/HCTZ 50/12.5MG TABLET	22-05-2013
02389673	MIN	[ST] MINT-LOSARTAN/HCTZ DS 100/25 TABLET	22-05-2013
02388766	MIN	[ST] MINT-METFORMIN 500MG TABLET	22-05-2013
02388774	MIN	[ST] MINT-METFORMIN 850MG TABLET	13-05-2013
02403587	APX	[ST] APO-MOMETASONE 50MCG NASAL SPRAY	17-04-2013
02389096	MAR	MAR-OLANZAPINE ODT 10MG	14-03-2013
02389118	MAR	MAR-OLANZAPINE ODT 15MG	14-03-2013
02389088	MAR	MAR-OLANZAPINE ODT 5MG	14-03-2013
02305054	APX	APO-OLOPATADINE 0.1% OPHTHALMIC SOLUTION	22-05-2013
02402483	STE	PILOCARPINE HCL 5MG TABLET	09-04-2013
80024835	JAP	[ST] JAMP-POTASSIUM CHLORIDE LIQUIDE	14-03-2013
99100951	UNK	PROCHLORPERAZINE TABLET 10MG (PQ)	28-05-2013
02388359	TEP	[ST] TEVA-RAMIPRIL/HCTZ 10/12.5MG TABLET	08-03-2013
02388375	TEP	[ST] TEVA-RAMIPRIL/HCTZ 10/25MG TABLET	08-03-2013
02388332	TEP	[ST] TEVA-RAMIPRIL/HCTZ 2.5/12.5MG TABLET	08-03-2013
02388340	TEP	[ST] TEVA-RAMIPRIL/HCTZ 5/12.5MG TABLET	08-03-2013
02388367	TEP	[ST] TEVA-RAMIPRIL/HCTZ 5/25MG TABLET	08-03-2013
02380056	RIV	[ST] RIVA-ROSUVASTATIN 10MG TABLET	09-04-2013
02380064	RIV	[ST] RIVA-ROSUVASTATIN 20MG TABLET	09-04-2013
02380102	RIV	[ST] RIVA-ROSUVASTATIN 40MG TABLET	09-04-2013
02380013	RIV	[ST] RIVA-ROSUVASTATIN 5MG TABLET	09-04-2013
80009595	JAP	[ST] JAMP-SENNA TABLET	08-03-2013
80024394	JAP	[ST] JAMP-SENNAQUIL 8.5MG/5ML LIQUIDE	08-03-2013
02395223	PDL	[ST] TELMISARTAN 40MG TABLET	10-04-2013
02395231	PDL	[ST] TELMISARTAN 80MG TABLET	10-04-2013
02401665	PMS	[ST] PMS-TELMISARTAN-HCTZ 80/12.5MG TABLET	05-06-2013
02395525	PDL	[ST] TELMISARTAN/HCTZ 80/12.5MG TABLET	10-04-2013
02395533	PDL	[ST] TELMISARTAN/HCTZ 80/25MG TABLET	10-04-2013
02402424	PMS	PMS-TETRABENAZINE 25MG TABLET	08-03-2013
02401231	STE	TRANEXAMIC ACID 500MG TABLET	09-04-2013
02299305	DOM	DOM-VENLAFAXINE XR 75MG CAPSULE	06-06-2013

NEW LIMITED USE BENEFITS

DIN	MFR	ITEM NAME	Effective Date
02377233	BMS	ELIQUIS 2.5MG TABLET	19-10-2012

Limited use benefit (prior approval not required).
-For the prevention of venous thromboembolism following total knee replacement or total hip replacement surgery, for up to 38 days.

09991146	ALL	BOTOX 200UNIT/VIAL INJECTION	26-03-2013

Limited use benefit (prior approval required).
a. For the treatment of urinary incontinence due to neurogenic detrusor over activity resulting from neurogenic bladder associated with MS or SCI (spinal cord injury) neurogenic bladder for clients who fail to respond to behaviour modification and anticholinergics and/or are intolerant to anticholinergics.

DIN	MFR	ITEM NAME	Effective Date
02394820	PDL	[ST] CLOPIDOGREL 75MG TABLET	03-06-2013

Limited use benefit (prior approval required).
a. Patients with intra-coronary stent implantation following insertion.
b. Patients with acute coronary syndrome (ACS) (unstable angina or non-ST-segment elevation MI), in combination with ASA.

02400553	SAN	[ST] CLOPIDOGREL 75MG TABLET	05-06-2013

Limited use benefit (prior approval required).
a. Patients with intra-coronary stent implantation following insertion.
b. Patients with acute coronary syndrome (ACS) (unstable angina or non-ST-segment elevation MI), in combination with ASA.

02312441	BOE	PRADAXA 110MG CAPSULE	27-05-2013
02358808	BOE	PRADAXA 150MG CAPSULE	27-05-2013

For at risk patients (CHADS2 score of ≥1) with non-valvular atrial fibrillation who require dabigatran for the prevention of stroke and systemic embolism AND in whom:

a. Anticoagulation is inadequate with a 2-month trial of warfarin; OR
b. Anticoagulation with warfarin is contraindicated; OR
c. Anticoagulation with warfarin is not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e., no access to INR testing service at a laboratory, clinic, pharmacy, and at home)

Exclusion Criteria:
· Patients with impaired renal function (CrCl or estimated GFR < 30 mL/min)
· Patients ≥ 75 years of age AND without documented stable renal function
· Patients with hemodynamically significant rheumatic valvular heart disease especially mitral stenosis
· Patients with prosthetic heart valves

Notes:
a. Documented stable renal function is defined as CrCl or estimated GFR that is maintained for at least 3 months (i.e., 30-49 mL/min for 110 mg twice daily or ≥50 mL/min for 150 mg twice daily dosing)
b. Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (please see product monograph).
c. Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.
There is currently no data to support that dabigatran provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so dabigatran is not recommended in these populations.

02374900	BAY	VISANNE 2MG TABLET	10-06-2013

Limited use benefit (prior approval required).
a. For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options are either ineffective or cannot be used.

02396955	APX	APO-ENTECAVIR 0.5MG TABLET	01-03-2013

Limited use benefit (prior approval required).
a. 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.

02355337	APX	APO-IMATINIB 100MG TABLET	23-04-2013
02355345	APX	APO-IMATINIB 400MG TABLET	23-04-2013
02399806	TEP	TEVA-IMATINIB 100MG TABLET	23-04-2013
02399814	TEP	TEVA-IMATINIB 400MG TABLET	23-04-2013

Limited use benefit (prior approval required).
a. For the treatment of patients with chronic myeloid leukemia in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.
b. For the treatment of patients with gastrointestinal stromal tumour.
c. For newly diagnosed adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (CML).

DIN	MFR	ITEM NAME	Effective Date
02239505	VAE	ALDARA 50MG/G CREAM	01-02-2013

Limited use benefit (prior approval required).
For the treatment of condylomata acuminate (genital warts) in patients who have failed:
a. self-applied podophyllotoxin (podofilox 0.5% solution); OR
b. provider-applied podophyllum resin (10%-25%).

02376938	NOV	ONBREZ BREEZHALER 75MCG	26-03-2013

Limited use benefit (prior approval required).
a. For the treatment of chronic obstructive pulmonary disease (COPD) in patients not adequately controlled with ipratropium or tiotropium.
Coverage is limited to a maximum dose of 75 mcg per day.

02357623	UCB	VIMPAT 100MG TABLET	01-04-2013
02357631	UCB	VIMPAT 150MG TABLET	01-04-2013
02357658	UCB	VIMPAT 200MG TABLET	01-04-2013
02357615	UCB	VIMPAT 50MG TABLET	01-04-2013

Limited use benefit (prior approval required).
For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:
a. Are under the care of a physician experienced in the treatment of epilepsy, AND
b. Are currently receiving two or more antiepileptic medications, AND
c. Have failed or demonstrated intolerance to at least two other antiepileptic medications.

02395258	PMS	[ST] PMS-LANSOPRAZOLE 15MG CAPSULE	06-06-2013
02395266	PMS	[ST] PMS-LANSOPRAZOLE 30MG CAPSULE	06-06-2013

Limited use benefit (prior approval not required).
Coverage will be limited to 400 tablets/capsules every 180 days.

02370921	BOE	[ST] TRAJENTA 5MG TABLET	27-05-2013

Limited use benefit (prior approval required).
a. Type 2 diabetes mellitus patients who are not adequately controlled by an adequate trial of metformin AND sulfonylureas or for whom these products are contraindicated or not tolerated.

02333430	DOM	DOM-OMEPRAZOLE DR 20MG TABLET	14-03-2013

Limited use benefit (prior approval not required).
Coverage will be limited to 400 tablets/capsules every 180 days.

96899961	AUC	OPTICHAMBER DIAMOND (CHAMBER)	28-05-2013
96899958	AUC	OPTICHAMBER DIAMOND (LARGE MASK)	28-05-2013
96899959	AUC	OPTICHAMBER DIAMOND (MEDIUM MASK)	28-05-2013
96899960	AUC	OPTICHAMBER DIAMOND (SMALL MASK)	28-05-2013

Limited use benefit (prior approval not required).
Coverage will be limited to one spacer device per year.

02339595	ACC	[ST] PIOGLITAZONE HCL 45MG TABLET	18-02-2013

Limited use benefit (prior approval required).
For treatment of type 2 diabetic patients who are not adequately controlled by or are intolerant to metformin and sulfonylureas or for whom these products are contraindicated.

DIN	MFR	ITEM NAME	Effective Date
02394278	APX	APO-PREGABALIN 150MG CAPSULE	30-04-2013
02394235	APX	APO-PREGABALIN 25MG CAPSULE	30-04-2013
02394294	APX	APO-PREGABALIN 300MG CAPSULE	30-04-2013
02394243	APX	APO-PREGABALIN 50MG CAPSULE	30-04-2013
02394251	APX	APO-PREGABALIN 75MG CAPSULE	30-04-2013
02402955	CBT	CO PREGABALIN 150MG CAPSULE	06-06-2013
02402912	CBT	CO PREGABALIN 25MG CAPSULE	06-06-2013
02402998	CBT	CO PREGABALIN 300MG CAPSULE	06-06-2013
02402920	CBT	CO PREGABALIN 50MG CAPSULE	06-06-2013
02402939	CBT	CO PREGABALIN 75MG CAPSULE	06-06-2013
02360179	PFI	GD-PREGABALIN 150MG CAPSULE	30-04-2013
02360136	PFI	GD-PREGABALIN 25MG CAPSULE	30-04-2013
02360209	PFI	GD-PREGABALIN 300MG CAPSULE	30-04-2013
02360144	PFI	GD-PREGABALIN 50MG CAPSULE	30-04-2013
02360152	PFI	GD-PREGABALIN 75MG CAPSULE	30-04-2013
02268450	PFI	LYRICA 150MG CAPSULE	30-04-2013
02268418	PFI	LYRICA 25MG CAPSULE	30-04-2013
02268485	PFI	LYRICA 300MG CAPSULE	30-04-2013
02268426	PFI	LYRICA 50MG CAPSULE	30-04-2013
02268434	PFI	LYRICA 75MG CAPSULE	30-04-2013
02359634	PMS	PMS-PREGABALIN 150MG CAPSULE	06-06-2013
02359596	PMS	PMS-PREGABALIN 25MG CAPSULE	06-06-2013
02359642	PMS	PMS-PREGABALIN 300MG CAPSULE	06-06-2013
02359618	PMS	PMS-PREGABALIN 50MG CAPSULE	06-06-2013
02359626	PMS	PMS-PREGABALIN 75MG CAPSULE	06-06-2013
02392844	RBY	RAN-PREGABALIN 150MG CAPSULE	30-04-2013
02392801	RBY	RAN-PREGABALIN 25MG CAPSULE	30-04-2013
02392860	RBY	RAN-PREGABALIN 300MG CAPSULE	30-04-2013
02392828	RBY	RAN-PREGABALIN 50MG CAPSULE	30-04-2013
02392836	RBY	RAN-PREGABALIN 75MG CAPSULE	30-04-2013
02390841	SDZ	SANDOZ PREGABALIN 150MG CAPSULE	06-06-2013
02390817	SDZ	SANDOZ PREGABALIN 25MG CAPSULE	06-06-2013
02390868	SDZ	SANDOZ PREGABALIN 300MG CAPSULE	06-06-2013
02390825	SDZ	SANDOZ PREGABALIN 50MG CAPSULE	06-06-2013
02390833	SDZ	SANDOZ PREGABALIN 75MG CAPSULE	06-06-2013
02361205	TEP	TEVA-PREGABALIN 150MG CAPSULE	30-04-2013
02361159	TEP	TEVA-PREGABALIN 25MG CAPSULE	30-04-2013
02361248	TEP	TEVA-PREGABALIN 300MG CAPSULE	30-04-2013
02361175	TEP	TEVA-PREGABALIN 50MG CAPSULE	30-04-2013
02361183	TEP	TEVA-PREGABALIN 75MG CAPSULE	30-04-2013

Limited use benefit (prior approval required).

a. For the treatment of neuropathic pain in patients who have failed to effective treat their pain with a tricyclic antidepressant (TCA); OR

b. For the treatment of neuropathic pain in patients who have a contraindication or intolerance with a tricyclic antidepressant (TCA).

DIN	MFR	ITEM NAME	Effective Date
02296810	NOV	LUCENTIS SOLUTION 10MG/ML	06-05-2013

Limited use benefit (prior approval required).
For the treatment of:
a. Diabetic Macular Edema (DME)
b. Wet Age-Related Macular Degeneration (w-AMD)

Criteria for coverage of ranibizumab (Lucentis) for DME and w-AMD:
• Administered by a qualified ophthalmologist experienced in intravitreal injections
• Interval between doses not shorter than 1 month
Note: Coverage will be limited to a maximum of 1 vial of Lucentis per eye treated every 30 days

For the treatment of diabetic macular edema (DME) for patients who meet the following:
• Clinically significant diabetic macular edema for whom laser photocoagulation is also indicated; AND
• Have a hemoglobin A1c of less than 11%

Initial Coverage for the treatment of neovascular wet age-related macular degeneration (wAMD) where all of the following apply to the eye to be treated:
• Best Corrected Visual Acuity (BCVA) is between 6/12 and 6/96
• The lesion size is less than or equal to 12 disc areas in greatest linear dimension
• There is evidence of recent (< 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT))

Note: Coverage will not be approved for patients:
• With permanent retinal damage as defined by the Royal College of Ophthalmology guidelines.
• Receiving concurrent treatment with verteporfin

Continued Coverage:

Treatment with Lucentis for wAMD should be continued only in people who maintain adequate response to therapy

Treatment with Lucentis should be permanently discontinued if any one of the following occurs:
• Reduction in BCVA in the treated eye to less than 15 letters (absolute) on two (2) consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
• Reductions in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate either poor treatment effect, adverse events or both.
• There is evidence of deterioration of the lesion morphology despite optimum treatment over three (3) consecutive visits.

DIN	MFR	ITEM NAME	Effective Date
02378604	BAY	XARELTO 15MG TABLET	15-04-2013
02378612	BAY	XARELTO 20MG TABLET	15-04-2013

Limited use benefit (prior approval required)

For the prevention of stroke and systemic embolism in at-risk patients (CHADS2 score of ≥1)who have non-valvular atrial fibrillation (AF) AND in whom:
a. Anticoagulation is inadequate following a reasonable trial on warfarin (2 months), OR
b. Anticoagulation with warfarin is contraindicated, OR
c. Not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e., no access to INR testing service at a laboratory, clinic, pharmacy, and at home)

Exclusion criteria:
· Patients with impaired renal function (CrCl or estimated GFR < 30 mL/min); OR
· Patients ≥ 75 years of age AND without documented stable renal function; OR
· Patients with hemodynamically significant rheumatic valvular heart disease especially mitral stenosis; OR
· Patients with prosthetic heart valves

Notes:
a) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least 3 months (i.e., 30-49mL/min for 15mg once daily dosing or ≥ 50mL/min for 20mg once daily dosing for at least 3 months).
b) At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of ≥ 1. Although the ROCKET-AF trial included patients with higher CHADS2 score (≥ 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a CHADS2 score of 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients with a CHADS2 score of 1.
c) Inadequate anticoagulation" is defined as INR testing results that are outside of the desired INR range for at least 35% of the tests during the monitoring period (i.e., adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
d) A reasonable trial on warfarin is defined as at least 2 months of therapy
e) Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see Xarelto product monograph).
f) Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.
g) There is currently no data to support that rivaroxaban provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so rivaroxaban is not recommended in these populations.

02396203	DOM	DOM-RIZATRIPTAN RDT 10MG	06-06-2013

Limited use benefit (prior approval not required).
Coverage will be limited to a maximum of 12 units per 30 days.

02389525	DOM	DOM-ZOLMITRIPTAN 2.5MG TABLET	10-04-2013

Limited use benefit (prior approval not required).
Coverage will be limited to a maximum of 12 units per 30 days.

CRITERIA CHANGES

LISTING CHANGE FOR NABILONE (CESAMET)

Effective April 30, 2013, the listing status of nabilone (Cesamet) has changed from open benefit to limited use.

The criteria is:
a.- For patients who are experiencing nausea and vomiting due to cancer chemotherapy or radiation; OR
b.- Patient is palliative (diagnosed with a terminal illness or disease which is expected to be the primary cause of death within six months or less).

Coverage will be granted for a maximum of six months. If coverage is required beyond the initial six months additional coverage may be reviewed on a case-by-case basis.

LISTING CHANGE FOR DEMEROL

Effective July 9, 2013, NIHB changed the listing status for oral and injectable meperidine from open benefit to exclusion.

RIVAROXABAN (XARELTO) 10MG CRITERIA CHANGE

Rivaroxaban (Xarelto) 10mg now has a maximum coverage period of 35 days for the prevention of venous thromboembolism following total knee replacement or total hip replacement surgery.

DELISTING OF PRODUCTS CONTAINING CODEINE FOR CHILDREN LESS THAN 12 YEARS OF AGE

Health Canada's Marketed Health Products Directorate has reviewed the safety of prescription pain and cough medications containing codeine and is no longer recommending their use in children less than 12 years of age.

The NIHB Program provides coverage for codeine as syrup and tablets and in combination with acetaminophen and ASA in products such Tylenol # 2 and 282s. However, as a result of Health Canada's latest recommendation, effective June 7, 2013, the NIHB Program no longer provides coverage for codeine or codeine-containing products for children under 12 years of age.

For more information, please visit: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/33915a-eng.php

LISTING CHANGE FOR MAGIC BULLET

Effective May 29, 2013, the listing status of Magic Bullet has changed from limited use to open benefit.