Health Canada Santé Canada

Fall-Winter 2011

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 Pharmacy and Therapeutics Committee (PT). 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 PT 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
09857178	ROC	ACCU-CHEK AVIVA STRIP (ON)	01-09-2011
09857293	BAY	ASCENSIA BREEZE 2 STRIP (ON)	01-09-2011
09857297	ABB	FREESTYLE LITE (ON)	20-09-2011
09857348	AUC	ITEST (ON)	28-09-2011
09857313	NCA	NOVA MAX	20-09-2011
09857283	AUC	TRUETRACK (ON)	20-09-2011
02352664	PFI	FRAGMIN 12,500IU/0.5ML SYRINGE	15-06-2011
02352672	PFI	FRAGMIN 15,000IU/0.6ML SYRINGE	17-06-2011
02352680	PFI	FRAGMIN 18,000IU/0.72ML SYRINGE	13-06-2011
02325462	NOO	VAGIFEM LD 10MCG VAGINAL TABLET	25-10-2011
02333619	NOO	GLUCAGEN 1MG/VIAL INJECTION	21-07-2011
02333627	NOO	GLUCAGEN HYPOKIT 1MG/ML INJECTION	21-07-2011
80021088	SPL	CORTATE CREAM 0.5%	17-10-2011

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

Canada

DIN	MFR	ITEM NAME	Effective Date
80021087	SPL	CORTATE LOTION 0.5%	17-10-2011
80021085	SPL	CORTATE OINTMENT 0.5%	17-10-2011
02250624	FRS	LACRISERT	10-10-2011
99100157	AUT	LACTEEZE DROPS	21-07-2011
97799945	ROC	SOFTCLIX LANCETS 200 (NS)	01-11-2011
02366282	PDL	ST LANSOPRAZOLE 30MG CAPSULE	07-11-2011
02364905	CBT	NEXT CHOICE	21-07-2011
80020794	PFI	ST CENTRUM JUNIOR COMPLETE TABLET	14-09-2011
02267233	NCC	ST TECTA 40MG TABLET	06-07-2011
02357593	ABB	NORVIR 100MG TABLET	06-07-2011
00614246	WHR	COMPOUND W GEL 170MG/ML	24-06-2011
80024901	SDZ	SALINEX DROPS	01-11-2011
80024381	SDZ	SALINEX NASAL SPRAY	07-09-2011
02358174	LEO	INNOHEP 14000 UNIT	04-11-2011
02358182	LEO	INNOHEP 18000 UNIT	04-11-2011
02358158	LEO	INNOHEP 3500 UNIT	04-11-2011
02358166	LEO	INNOHEP 4500IU/0.45ML INJECTION	04-11-2011

Multi-Source Drug Products

DIN	MFR	ITEM NAME	Effective Date
02243801	PMS	ST EQUATE DAILY LOW-DOSE 81MG ECT	03-08-2011
02364336	SAN	ST AMIODARONE 200MG TABLET	31-08-2011
02357208	JAP	ST JAMP-AMLODIPINE 10MG TABLET	26-10-2011
02357194	JAP	ST JAMP-AMLODIPINE 5MG TABLET	26-10-2011
02371723	MAR	ST MAR-AMLODIPINE 10MG TABLET	07-11-2011
02371707	MAR	ST MAR-AMLODIPINE 2.5MG TABLET	07-11-2011
02371715	MAR	ST MAR-AMLODIPINE 5MG TABLET	07-11-2011
02362791	PFI	ST GD-AMLODIPINE/ATORVAST 10/10MG	26-10-2011
02362805	PFI	ST GD-AMLODIPINE/ATORVAST 10/20MG	25-10-2011
02362813	PFI	ST GD-AMLODIPINE/ATORVAST 10/40MG	26-10-2011
02362821	PFI	ST GD-AMLODIPINE/ATORVAST 10/80MG	26-10-2011
02362759	PFI	ST GD-AMLODIPINE/ATORVAST 5/10MG	26-10-2011
02362767	PFI	ST GD-AMLODIPINE/ATORVAST 5/20MG	26-10-2011
02362775	PFI	ST GD-AMLODIPINE/ATORVAST 5/40MG	26-10-2011
02362783	PFI	ST GD-AMLODIPINE/ATORVAST 5/80MG	26-10-2011
02371995	MAR	ST MAR-ATENOLOL 100MG TABLET	07-11-2011
02371979	MAR	ST MAR-ATENOLOL 25MG TABLET	07-11-2011
02371987	MAR	ST MAR-ATENOLOL 50MG TABLET	07-11-2011
02368048	MIN	ST MINT-ATENOLOL 100MG TABLET	21-07-2011
02368013	MIN	ST MINT-ATENOLOL 25MG TABLET	21-07-2011
02368021	MIN	ST MINT-ATENOLOL 50MG TABLET	21-07-2011
02331616	PDL	BUPROPION SR 100MG TABLET	01-07-2011
02275082	SDZ	SANDOZ-BUPROPION SR 150MG TABLET	01-07-2011
80013329	MAN	ST M-CAL D TABLET	07-11-2011
80004968	TRI	ST CALCIUM D 500 TABLET	01-09-2011
80019536	MAN	ST M-CAL D 1000 TABLET	07-11-2011
80009412	MAN	ST M-CAL D 400 CHEWTABLET	07-11-2011
80019533	MAN	ST M-CAL D 800 TABLET	07-11-2011
02364948	SAN	ST CARVEDILOL 12.5MG TABLET	31-08-2011
02364956	SAN	ST CARVEDILOL 25MG TABLET	31-08-2011
02364913	SAN	ST CARVEDILOL 3.125MG TABLET	31-08-2011
02364921	SAN	ST CARVEDILOL 6.25MG TABLET	31-08-2011
02371871	MAR	MAR-CITALOPRAM 10MG TABLET	07-11-2011
02371898	MAR	MAR-CITALOPRAM 20MG TABLET	07-11-2011
02371901	MAR	MAR-CITALOPRAM 40MG TABLET	07-11-2011
02370077	MIN	MINT-CITALOPRAM 10MG TABLET	07-11-2011

DIN	MFR	ITEM NAME	Effective Date
02361299	SAN	[ST] CLONIDINE 0.025MG TABLET	31-08-2011
02361302	SAN	[ST] CLONIDINE 0.1MG TABLET	31-08-2011
02361310	SAN	[ST] CLONIDINE 0.2MG TABLET	31-08-2011
02285843	PFI	GD-GABAPENTIN 600MG TABLET	02-08-2011
02360594	SAN	[ST] HYDROCHLOROTHIAZIDE 25MG TABLET	31-08-2011
02360608	SAN	[ST] HYDROCHLOROTHIAZIDE 50MG TABLET	31-08-2011
02365200	PDL	[ST] IRBESARTAN 150MG TABLET	07-11-2011
02365219	PDL	[ST] IRBESARTAN 300MG TABLET	07-11-2011
02365197	PDL	[ST] IRBESARTAN 75MG TABLET	07-11-2011
02365162	PDL	[ST] IRBESARTAN-HCTZ 150/12.5MG TABLET	07-11-2011
02365170	PDL	[ST] IRBESARTAN-HCTZ 300/12.5MG TABLET	07-11-2011
02365189	PDL	[ST] IRBESARTAN-HCTZ 300/25MG TABLET	07-11-2011
02296527	APX	APO-LATANOPROST 50MCG/ML OPHTHALMIC SOLUTION	13-10-2011
02373424	MAR	MAR-LETROZOLE 2.5MG TABLET	07-11-2011
02372169	MYL	MYL-LETROZOLE 2.5MG TABLET	13-10-2011
02362945	SAN	[ST] LISINOPRIL/HCTZ (Z) 10/12.5MG	31-08-2011
02362953	SAN	[ST] LISINOPRIL/HCTZ (Z) 20/12.5MG	31-08-2011
02362961	SAN	[ST] LISINOPRIL/HCTZ (Z) 20/25MG	31-08-2011
02299801	AUR	AURO-MIRTAZAPINE OD 15MG TABLET	29-07-2011
02299828	AUR	AURO-MIRTAZAPINE OD 30MG TABLET	28-07-2011
02299836	AUR	AURO-MIRTAZAPINE OD 45MG TABLET	29-07-2011
02367157	TAR	TARO-MOMETASONE 0.1% CR	21-07-2011
02318601	AUR	AURO-NEVIRAPINE 200MG TABLET	21-07-2011
02337908	MYL	MYLAN-OLANZAPINE 10MG TABLET	21-07-2011
02337916	MYL	MYLAN-OLANZAPINE 15MG TABLET	21-07-2011
02337878	MYL	MYLAN-OLANZAPINE 2.5MG TABLET	21-07-2011
02337886	MYL	MYLAN-OLANZAPINE 5MG TABLET	21-07-2011
02337894	MYL	MYLAN-OLANZAPINE 7.5MG TABLET	21-07-2011
02371731	MAR	MAR-ONDANSETRON 4MG TABLET	07-11-2011
02361361	SAN	OXYCODONE/ACET 5/325MG TABLET	06-09-2011
02367378	MYL	[ST] MYL-RANITIDINE 150MG TABLET	13-06-2011
02367378	MYL	[ST] MYL-RANITIDINE 150MG TABLET	04-07-2011
02367386	MYL	[ST] MYL-RANITIDINE 300MG TABLET	04-07-2011
02357453	SDZ	[ST] SANDOZ REPAGLINIDE 0.5MG TABLET	21-07-2011
02357461	SDZ	[ST] SANDOZ REPAGLINIDE 1MG TABLET	21-07-2011
02357488	PFI	[ST] SANDOZ REPAGLINIDE 2MG TABLET	21-07-2011
02371766	MAR	MAR-RISPERIDONE 0.25MG TABLET	07-11-2011
02371774	MAR	MAR-RISPERIDONE 0.5MG TABLET	07-11-2011
02371782	MAR	MAR-RISPERIDONE 1MG TABLET	07-11-2011
02371790	MAR	MAR-RISPERIDONE 2MG TABLET	07-11-2011
02371804	MAR	MAR-RISPERIDONE 3MG TABLET	07-11-2011
02371812	MAR	MAR-RISPERIDONE 4MG TABLET	07-11-2011
02291789	PMS	PMS-RISPERIDONE ODT 1MG RD TABLET	21-07-2011
02291797	PMS	PMS-RISPERIDONE ODT 2MG RD TABLET	21-07-2011
02361698	SUN	SUMATRIPTAN SUN 6MG/0.5ML INJECTION	14-06-2011
02362406	APX	[ST] APO-TAMSULOSIN CR 0.4MG TABLET	13-10-2011
02371537	APX	[ST] APO-VALSARTAN 160MG TABLET	13-10-2011
02371545	APX	[ST] APO-VALSARTAN 320MG TABLET	13-10-2011
02371510	APX	[ST] APO-VALSARTAN 40MG TABLET	13-10-2011
02371529	APX	[ST] APO-VALSARTAN 80MG TABLET	13-10-2011
02337509	CBT	[ST] CO VALSARTAN 160 MG TABLET	14-06-2011
02337517	CBT	[ST] CO VALSARTAN 320 MG TABLET	14-06-2011
02337487	CBT	[ST] CO VALSARTAN 40 MG TABLET	14-06-2011
02337495	CBT	[ST] CO VALSARTAN 80 MG TABLET	14-06-2011
02367742	PDL	[ST] VALSARTAN 160MG TABLET	07-11-2011
02367750	PDL	[ST] VALSARTAN 320MG TABLET	07-11-2011

DIN	MFR	ITEM NAME	Effective Date
02367726	PDL	[ST] VALSARTAN 40MG TABLET	07-11-2011
02367734	PDL	[ST] VALSARTAN 80MG TABLET	07-11-2011
02367777	PDL	[ST] VALSARTAN-HCTZ 160/12.5MG TABLET	07-11-2011
02367785	PDL	[ST] VALSARTAN-HCTZ 160/25MG TABLET	07-11-2011
02367769	PDL	[ST] VALSARTAN-HCTZ 80/12.5MG TABLET	07-11-2011
02339269	PDL	VENLAFAXINE XR 150MG CAPSULE	31-08-2011
02339242	PDL	VENLAFAXINE XR 37.5MG CAPSULE	31-08-2011
02339250	PDL	VENLAFAXINE XR 75MG CAPSULE	31-08-2011
80009580	SWS	[ST] VITAMIN D 1000IU TABLET	28-09-2011
80002452	WNP	[ST] VITAMIN D 400IU TABLET	29-09-2011
80009578	SWS	[ST] VITAMIN D 400IU TABLET	30-09-2011
00122831	JAM	[ST] VITAMIN E CAP 200IU NATURAL SOURCE	27-06-2011
02369036	MYL	MYLAN ZOLMITRIPTAN 2.5MG TABLET	21-07-2011
02324229	PMS	PMS-ZOLMITRIPTAN 2.5MG TABLET	15-06-2011
02324768	PMS	PMS-ZOLMITRIPTAN ODT 2.5MG	22-06-2011
02362988	SDZ	SANDOZ ZOLMITRIPTAN 2.5MG TABLET	15-06-2011
02362996	SDZ	SANDOZ ZOLMITRIPTAN ODT 2.5MG	15-06-2011
02313960	TEP	TEVA-ZOLMITRIPTAN 2.5MG TABLET	15-06-2011
02342545	TEP	TEVA-ZOLMITRIPTAN OD 2.5MG	15-06-2011

NEW LIMITED USE BENEFITS

DIN	MFR	ITEM NAME	Effective Date
02331667	AST	ADVAGRAF 3MG ER CAPSULE	07-11-2011

Limited use benefit (prior approval required).
For transplant therapy.

DIN	MFR	ITEM NAME	Effective Date
02357984	MYL	[ST] MYLAN-RISEDRONATE 35MG TABLET	13-10-2011

Limited use benefit (prior approval required).
- 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 in patients under 60 who will be or have been on systemic corticosteriod therapy of prednisone 7.5mg per day or equivalent for > 3 months. Approval period of 1 year.

DIN	MFR	ITEM NAME	Effective Date
02358921	PMS	PMS-RALOXIFENE 60MG TABLET	13-10-2011

Limited use benefit (prior approval required).
a. Secondary prevention of osteoporosis in women who experience failure on bisphosphonates; OR
b. Secondary prevention of osteoporosis in women who have a personal history or a first degree relative with a history of breast cancer.

DIN	MFR	ITEM NAME	Effective Date
02328593	SDZ	SANDOZ MONTELUKAST 10MG TABLET	07-11-2011
02330385	TEP	SANDOZ MONTELUKAST 4MG CHEWABLE TABLET	07-11-2011
02330393	TEP	SANDOZ MONTELUKAST 5MG CHEWABLE TABLET	07-11-2011
02354977	PMS	PMS-MONTELUKAST 4MG CHEWABLE TABLET	07-11-2011
02354985	PMS	PMS-MONTELUKAST 5MG CHEWABLE TABLET	07-11-2011
02355507	TEP	TEVA-MONTELUKAST 4MG CHEWABLE TABLET	07-11-2011
02355515	TEP	TEVA MONTELUKAST 5MG CHEWABLE TABLET	07-11-2011
02355523	TEP	TEVA MONTELUKAST 10MG TABLET	07-11-2011
02358611	SDZ	SANDOZ MONTELUKAST GRANULES	07-11-2011
02368226	MYL	MYLAN-MONTELUKAST 10MG TABLET	07-11-2011
02373947	PMS	PMS-MONTELUKAST FC 10MG TABLET	07-11-2011
02374609	APX	APO-MONTELUKAST 10MG TABLET	07-11-2011

Limited use benefit (prior approval required).
For treatment of:
a. Asthma when used in patients on concurrent steroid therapy; OR
b. Asthma patients not well controlled with or intolerant to inhaled corticosteroids.

02359502	PFR	HYDROMORPH CONTIN 4.5MG CAPSULE	06-07-2011
02359510	PFR	HYDROMORPH CONTIN 9MG CAPSULE	06-07-2011

Limited use benefit (prior approval required).
For treatment of moderate to severe chronic pain when other long acting opioids such as morphine have been ineffective in controlling pain or in patients experiencing intolerable side effects.

02365383	APX	[ST] APO-FINASTERIDE 5MG TABLET	21-07-2011

Limited use benefit (prior approval required).
a. For treatment of Benign Prostatic Hyperplasia (BPH) in patients who do not tolerate or have not responded to an alpha adrenergic blocker; OR
b. For use in combination therapy when monotherapy with an alpha-blocker is not sufficient.

02357380	TAK	ULORIC 80MG TABLET	24-08-2011

Limited use benefit (prior approval required).
For patients with symptomatic gout who have documented hypersensitivity to allopurinol

02343541	AMG	PROLIA 60MG/ML PRE-FILLED SYRINGE	18-10-2011
02343568	AMG	PROLIA 60MG/ML VIAL	18-10-2011

Limited use benefit (prior approval required).
For women with postmenopausal osteoporosis who would otherwise be eligible for coverage of oral bisphosphonates, but for whom:
- bisphosphonates are contraindicated due to hypersensitivity or abnormalities of the esophagus (e.g., esophageal stricture or achalasia); AND
Have at least two of the following:
- age >70 years
- a prior fragility fracture
- a bone mineral density (BMD) T-score ≤ -2.5

02322374	BMS	ABILIFY 2MG TABLET	29-07-2011
02322382	BMS	ABILIFY 5MG TABLET	29-07-2011
02322390	BMS	ABILIFY 10MG TABLET	29-07-2011
02322404	BMS	ABILIFY 15MG TABLET	29-07-2011
02322412	BMS	ABILIFY 20MG TABLET	29-07-2011
02322455	BMS	ABILIFY 30MG TABLET	29-07-2011

Limited use benefit (prior approval required).
For the treatment of schizophrenia and schizoaffective disorders in patients who have
a. Intolerance or lack of response to an adequate trial of another antipsychotic agent; OR
b. A contraindication to another antipsychotic agent

NOT ADDED TO FORMULARY

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

DIN	MFR	ITEM NAME
02370417	WAC	ACTONEL DR 35MG TABLET
02359456	NCC	DAXAS 500MCG TABLET
02355655	ALL	RESTASIS 0.05% OPHTHALMIC SOLUTION
02245911	NUR	VITALUX

CRITERIA CHANGES

THIRTY (30) DAY SUPPLY LIMIT FOR FENTANYL PATCHES, CONTROLLED RELEASE HYDROMORPHONE AND CONTROLLED RELEASE CODEINE

On November 1, 2011, the NIHB Program introduced a day supply limit per dispense for Fentanyl Transdermal Patches, Controlled Release Hydromorphone Capsules and Controlled Release Codeine Tablets. The maximum day supply limit per dispense for items listed below is 30 days.

12mcg/h Transdermal Patch
02341379 PMS-FENTANYL MTX PMS
02330105 RAN-FENTANYL MATRIX PATCH 12 RBY
02311925 RATIO-FENTANYL RPH
02327112 SANDOZ FENTANYL SDZ

25mcg/h Transdermal Patch
02275813 DURAGESIC MAT JNO
02314630 NOVO-FENTANYL NOP
02341387 PMS-FENTANYL MTX PMS
02249391 RAN-FENTANYL RBY
02330113 RAN-FENTANYL MATRIX RBY
02282941 RATIO-FENTANYL RPH
02327120 SANDOZ FENTANYL SDZ

50mcg/h Transdermal Patch
02275821 DURAGESIC MAT JNO
02314649 NOVO-FENTANYL NOP
02341395 PMS-FENTANYL MTX PMS
02249413 RAN-FENTANYL RBY
02330121 RATIO-FENTANYL RPH
02282968 RATIO-FENTANYL RPH
02327147 SANDOZ FENTANYL SDZ

75mcg/h Transdermal Patch
02275848 DURAGESIC MAT JNO
02314657 NOVO-FENTANYL NOP
02341409 PMS-FENTANYL MTX PMS
02249421 RAN-FENTANYL RBY
02330148 RAN-FENTANYL MATRIX RBY
02282976 RATIO-FENTANYL RPH
02327155 SANDOZ FENTANYL SDZ

100mcg/h Transdermal Patch
02275856 DURAGESIC MAT JNO
02314665 NOVO-FENTANYL NOP
02341417 PMS-FENTANYL MTX PMS
02249448 RAN-FENTANYL RBY
02330156 RAN-FENTANYL MATRIX RBY
02282984 RATIO-FENTANYL RPH
02327163 SANDOZ FENTANYL TRANSDERMAL SYSTEM SDZ

50mg Long Acting Tablet
02230302 CODEINE CONTIN CR PFR

100mg Long Acting Tablet
02163748 CODEINE CONTIN CR PFR

150mg Long Acting Tablet
02163780 CODEINE CONTIN CR PFR

200mg Long Acting Tablet
02163799 CODEINE CONTIN CR PFR

3mg Controlled Release Capsule
02125323 HYDROMORPH CONTIN PFR

6mg Controlled Release Capsule
02125331 HYDROMORPH CONTIN PFR

12mg Controlled Release Capsule
02125366 HYDROMORPH CONTIN PFR

18mg Controlled Release Capsule
02243562 HYDROMORPH CONTIN PFR

24mg Controlled Release Capsule
02125382 HYDROMORPH CONTIN PFR

30mg Controlled Release Capsule
02125390 HYDROMORPH CONTIN PFR

COVERAGE OF SUBOXONE

Effective December 7, 2011, Suboxone is listed on the NIHB DBL as a Limited Use benefit with the following criteria.

For the treatment of opioid dependence in patients who have a contraindication to methadone due to:

- Evidence of (or high risk for) QT interval prolongation; AND
- Prescribed by a physician with experience in substitution treatment in opioid drug dependence or completion of an accredited Suboxone Education Program.

Requests for Suboxone for use other than what is specified above will be reviewed on a case by case basis. NIHB clients who are approved for Suboxone coverage must agree to have restrictions that prevents the use of methadone or opioids, and ensures that benzodiazepine and stimulants are each prescribed by a sole prescriber.

REVISED CRITERIA FOR LEVETIRACETAM

The limited use criteria for levetiracetam has changed. The number of trials of anti-epileptic drugs that are required has changed from three to two.

The new criteria is:

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

REVISED CRITERIA FOR ALENDRONATE (FOSAMAX), ALENDRONATE + VITAMIN D (FOSAVANCE) AND RISEDRONATE (ACTONEL)

The limited use criteria for fosamax, fosavance and risedronate has changed.

The new criteria is:

- 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. Approval period of one year.