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Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – July 2020
Effective July 31, 2020

Drug Programs Policy and Strategy Branch
Drugs and Devices Division
Ministry of Health

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New Single Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02485575	Nivestym	300mcg/0.5mL	Inj Sol-0.5mL Pref Syr	FILGRASTIM	PFI	144.3100/Pref Syr
02485591	Nivestym	300mcg/mL	Inj Sol-1mL Vial Pk	FILGRASTIM	PFI	144.3100/Vial
02485583	Nivestym	480mcg/0.8mL	Inj Sol-0.8mL Pref Syr	FILGRASTIM	PFI	230.9000/Pref Syr
02485656	Nivestym	480mcg/1.6mL	Inj Sol-1.6mL Vial Pk	FILGRASTIM	PFI	230.9000/Vial

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02495724	Ruxience	10mg/mL	Inj Sol-Vial	RITUXIMAB	PFI	31.3502/mL

Reason For Use Code and Clinical Criteria

Code 583

For the treatment of adults with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria.

1. Patient has experienced failure to respond, documented intolerance, or contraindication to optimal use of one of the following disease modifying, anti-rheumatic (DMARD) regimens:

    A. i) Methotrexate (20mg/week) for at least 3 months, AND

    ii) Leflunomide (20mg/day) for at least 3 months, in addition to

    iii) An adequate trial of at least one combination of DMARDs for 3 months;

    OR

B. i) Methotrexate (20mg/week) for at least 3 months, AND

ii) Leflunomide in combination with methotrexate for at least 3 months; OR

C. i) Methotrexate (20mg/week), sulfasalazine (2g/day) and hydroxychloroquine (400mg/day) for at least 3 months.

(Hydroxychloroquine is based by weight up to 400mg per day.)

2. Patient has experienced failure to respond, documented intolerance, or contraindication to an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, golimumab, certolizumab pegol).

3. Patient is not using rituximab in a maintenance setting.

4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab.

5. Rituximab is not used in combination with another biologic to treat the patient's RA.

6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of treatment is 1000mg followed two weeks later by the second 1000mg dose.

LU Authorization Period: 3 months

Code 584

For the re-treatment of patients with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints, and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria:

1. Patient has met the initiation criteria for rituximab in accordance with RFU 583;

2. Patient has experienced loss of effect after having responded to the prior treatment course of rituximab (Response is defined as a 20% reduction in the swollen joint count compared to the joint count prior to the first, pre-treatment course evaluated at 3 to 4 months following the administered course AND improvement in 2 swollen joints); AND

3. Patient is not using rituximab in a maintenance setting; AND

4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab; AND

5. Rituximab is not used in combination with another biologic to treat the patient's RA.

6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of re-treatment is 1000mg followed two weeks later by the second 1000mg dose.

LU Authorization Period: 3 months

Code 585

Rituximab is used in combination with glucocorticoids for the induction of remission in patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA), for patients who meet all of the following criteria:

1. The patient must have severe active disease that is life- or organ-threatening as supported by laboratory and/or imaging reports

   AND

2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA.

   AND

3. Cyclophosphamide cannot be used by the Patient for **ONE** of the following reasons:

   a. The patient has failed a minimum of six IV pulses of cyclophosphamide; OR
   b. The patient has failed three months of oral cyclophosphamide therapy; OR
   c. The patient has a severe intolerance or an allergy to cyclophosphamide; OR
   d. Cyclophosphamide is contraindicated; OR
   e. The patient has received a cumulative lifetime dose of at least 25g of cyclophosphamide; OR
   f. The patient wishes to preserve ovarian/testicular function for fertility.

4. The request is from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The patient should not have received a course of rituximab in the prior 6 months.

The recommended dosing regimen for the initial treatment would be a once weekly infusion dosed at 375 milligrams per square metre x 4 weeks.

Case-by-case considerations for patients not meeting the LU criteria may be considered through the exceptional access program.

LU Authorization Period: 1 month (1 treatment course)

New Single Source Products (Continued)

Code 586

Rituximab (Ruxience) treatment will be used for patients with severely active Granulomatosis with Polyangiitis [(GPA), also known as Wegener's Granulomatosis (WG)] OR microscopic polyangiitis (MPA) who have achieved disease remission. Patient must meet all of the following criteria:

1. The patient must have severe active disease that is life- or organ-threatening as supported by laboratory and/or imaging reports
2. There is a positive serum assay for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA. A copy of the laboratory report must be provided.
3. Stabilization of the condition with induction doses of cyclophosphamide (injectable or oral doses are acceptable) and a glucocorticoid as combination over 4 to 6 months until disease remission prior to initiation of rituximab.
4. The request is from a prescriber experienced in the diagnosis and management of GPA, MPA, and vasculitis.

Exclusion criteria:

The patient should not have received a dose of rituximab in the prior 6 months. Doses of rituximab administered at intervals more frequently than every 6 months are not funded.

The recommended dosing regimen: A fixed dose regimen of Rituximab of 500mg IV every 6 months.

Case-by-case considerations for patients not meeting the LU criteria may be considered through the exceptional access program.

LU Authorization Period: 1 year

New Single Source Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02498316	Riximyo	10mg/mL	Inj Sol-Vial	RITUXIMAB	SDZ	30.3855/mL

Reason For Use Code and Clinical Criteria

Code 581

For the treatment of adults with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria.

1. Patient has experienced failure to respond, documented intolerance, or contraindication to optimal use of one of the following disease modifying, anti-rheumatic (DMARD) regimens:

A. i) Methotrexate (20mg/week) for at least 3 months, AND

ii) Leflunomide (20mg/day) for at least 3 months, in addition to

iii) An adequate trial of at least one combination of DMARDs for 3 months;

OR

B. i) Methotrexate (20mg/week) for at least 3 months, AND

ii) Leflunomide in combination with methotrexate for at least 3 months; OR

C. i) Methotrexate (20mg/week), sulfasalazine (2g/day) and hydroxychloroquine (400mg/day) for at least 3 months.

(Hydroxychloroquine is based by weight up to 400mg per day.)

2. Patient has experienced failure to respond, documented intolerance, or contraindication to an adequate trial of at least ONE anti-TNF agent (e.g., adalimumab, etanercept, infliximab, golimumab, certolizumab pegol).

3. Patient is not using rituximab in a maintenance setting.

4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab.

5. Rituximab is not used in combination with another biologic to treat the patient's RA.

6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of treatment is 1000mg followed two weeks later by the second 1000mg dose.

LU Authorization Period: 3 months

Code 582

For the re-treatment of patients with severe active rheumatoid arthritis (RA) (greater than or equal to 5 swollen joints, and rheumatoid factor positive and/or anti-CCP positive, and radiographic evidence of rheumatoid arthritis) who meet ALL the following criteria:

New Single Source Products (Continued)

1. Patient has met the initiation criteria for rituximab in accordance with RFU 581;

2. Patient has experienced loss of effect after having responded to the prior treatment course of rituximab (Response is defined as a 20% reduction in the swollen joint count compared to the joint count prior to the first, pre-treatment course evaluated at 3 to 4 months following the administered course AND improvement in 2 swollen joints); AND

3. Patient is not using rituximab in a maintenance setting; AND

4. Patient is not using a treatment course of rituximab earlier than 6 months after the completion of a prior course of rituximab; AND

5. Rituximab is not used in combination with another biologic to treat the patient's RA.

6. Treatment must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

One course of re-treatment is 1000mg followed two weeks later by the second 1000mg dose.

LU Authorization Period: 3 months

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New Multi-Source Products

Where applicable, please consult the respective brand reference product's drug profile on the ODB e-Formulary for the details of the Limited Use (LU) code and criteria, and/or any associated Therapeutic Notes (TN).

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02238796	Apo-Beclomethasone Nasal Spray	50mcg/dose	Nas-Sp-200 Dose Pk	APX	12.2600

(Interchangeable with Beconase Aqueous – GB with TN)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02247937	Apo-Hydroxyurea	500mg	Cap	APX	1.0203

(Interchangeable with Hydrea – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02497476	Mint-Oseltamivir	75mg	Cap	MIN	2.0785

(Interchangeable with Tamiflu – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02486369	Mint-Telmisartan	40mg	Tab	MIN	0.2161
02486377	Mint-Telmisartan	80mg	Tab	MIN	0.2161

(Interchangeable with Micardis – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02495457	Mint-Valganciclovir	450mg	Tab	MIN	5.8553

(Interchangeable with Valcyte – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02482126	NRA-Duloxetine	30mg	DR Cap	NRA	0.4814
02482134	NRA-Duloxetine	60mg	DR Cap	NRA	0.9769

(Interchangeable with Cymbalta – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02479761	NRA-Paroxetine	20mg	Tab	NRA	0.3250
02479788	NRA-Paroxetine	30mg	Tab	NRA	0.3453

(Interchangeable with Paxil – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02479117	NRA-Pregabalin	25mg	Cap	NRA	0.1481
02479125	NRA-Pregabalin	50mg	Cap	NRA	0.2324
02479133	NRA-Pregabalin	75mg	Cap	NRA	0.3007
02479168	NRA-Pregabalin	150mg	Cap	NRA	0.4145

(Interchangeable with Lyrica – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02489015	NRA-Perindopril	2mg	Tab	NRA	0.1632
02489023	NRA-Perindopril	4mg	Tab	NRA	0.2042
02489031	NRA-Perindopril	8mg	Tab	NRA	0.2831

(Interchangeable with Coversyl – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02023695	Atropine	1%	Oph Sol	PHS	0.5490/mL

(Interchangeable with Isopto Atropine – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02461323	Sandoz Gliclazide MR	30mg	ER Tab	SDZ	0.0931

(Interchangeable with Diamicron MR – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02481634	Perindopril Erbumine	2mg	Tab	SAI	0.1632
02481642	Perindopril Erbumine	4mg	Tab	SAI	0.2042
02481650	Perindopril Erbumine	8mg	Tab	SAI	0.2831

(Interchangeable with Coversyl – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02343053	Propafenone	150mg	Tab	SAI	0.2966
02343061	Propafenone	300mg	Tab	SAI	0.5227

(Interchangeable with Rythmol – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02388707	Candesartan	8mg	Tab	SIV	0.2281
02388715	Candesartan	16mg	Tab	SIV	0.2281

(Interchangeable with Atacand – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02445999	Diltiazem CD	120mg	ER Cap	SIV	0.3634
02446006	Diltiazem CD	180mg	ER Cap	SIV	0.4824
02446014	Diltiazem CD	240mg	ER Cap	SIV	0.6399
02446022	Diltiazem CD	300mg	ER Cap	SIV	0.7999

(Interchangeable with Cardizem CD – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02479877	Perindopril Erbumine	2mg	Tab	SIV	0.1632
02479885	Perindopril Erbumine	4mg	Tab	SIV	0.2042
02479893	Perindopril Erbumine	8mg	Tab	SIV	0.2831

(Interchangeable with Coversyl – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02403692	Pregabalin	25mg	Cap	SIV	0.1481
02403706	Pregabalin	50mg	Cap	SIV	0.2324
02403714	Pregabalin	75mg	Cap	SIV	0.3007
02403722	Pregabalin	150mg	Cap	SIV	0.4145
02403730	Pregabalin	300mg	Cap	SIV	0.4145

(Interchangeable with Lyrica – GB)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02384736	Valsartan HCT	80mg & 12.5mg	Tab	SIV	0.2213
02384744	Valsartan HCT	160mg & 12.5mg	Tab	SIV	0.2240
02384752	Valsartan HCT	160mg & 25mg	Tab	SIV	0.2238
02384760	Valsartan HCT	320mg & 12.5mg	Tab	SIV	0.2235

(Interchangeable with Diovan-HCT – GB)

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New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02496119	Accel-Pilocarpine	5mg	Tab	ACC	1.2445

(Interchangeable with Salagen)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02498758	Nat-Lanthanum	500mg	Chew Tab	NAT	2.0459
02498766	Nat-Lanthanum	750mg	Chew Tab	NAT	3.0786
02498774	Nat-Lanthanum	1000mg	Chew Tab	NAT	4.0815

(Interchangeable with Fosrenol)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02479753	NRA-Paroxetine	10mg	Tab	NRA	1.0430

(Interchangeable with Paxil)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02476819	NRA-Sildenafil	100mg	Tab	NRA	9.2006

(Interchangeable with Viagra)

New Off-Formulary Interchangeable (OFI) Products (Continued)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02421429	Atovaquone Proguanil	250mg & 100mg	Tab	SAI	4.1308

(Interchangeable with Malarone)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02431289	Gabapentin	600mg	Tab	SAI	1.3045
02431297	Gabapentin	800mg	Tab	SAI	1.7393

(Interchangeable with Neurontin)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02495023	Sandoz Clobetasol	0.05% w/w	Top Sol Sp	SDZ	1.9322/mL

(Interchangeable with Clobex Spray)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02486423	Teva-Teriparatide Injection	250mcg/mL	Inj Sol-2.4mL Pref Pen (with Preservative)	TEV	800.7934/ Pref Pen

(Interchangeable with Forteo PIN 09857535)

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Revision of Limited Use Criteria

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02467550	Maviret	100mg & 40mg	Tab	ABV

LU Code 550

For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, infectious disease specialist or other prescriber experienced in treating a patient with chronic hepatitis C;

(ii) Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, or 6;

(iii) Two Laboratory confirmed quantitative HCV RNA values taken at least 6 months apart as demonstration of chronicity of infection. One level must be within the last 6 months while the first level may be at the time of the initial diagnosis.

Exclusion criteria:

- Patients with genotype 1 who have relapsed but are treatment experienced on both an NS3/4A protease inhibitor and an NS5A inhibitor
- For use in combination with other hepatitis C antiviral agents
- Patients with decompensated cirrhosis or severe hepatic impairment (Child-Pugh C)

Retreatment is not funded. Retreatment for re-infection in patients who have received an adequate prior course of Maviret will be considered on a case-by-case basis through the Exceptional Access Program.

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Revision of Limited Use Criteria (Continued)

Treatment regimens for Maviret: **(Revisions are in bold)**

I. Treatment-naive, non-cirrhotic genotype 1, 2, 3, 4, 5, or 6.

Approved duration: 8 weeks

II. Treatment-naive genotype 1, 2, 4, 5, or 6 with compensated cirrhosis.

Approved duration: 8 weeks

III. Treatment-experienced, non-cirrhotic genotype 1, 2, 4, 5, or 6 who have failed peginterferon/ribavirin and/or sofosbuvir ONLY.

Approved duration: 8 weeks

Notes:

(1) Treatment-experienced definitions vary by the genotype being treated. Health care professionals are advised to refer to the Maviret product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(2) NS3/4A PIs include simeprevir, boceprevir, and telepravir.

(3) NS5A inhibitors include daclatasvir and ledipasvir.

LU Authorization Period: 8 weeks

Revision of Limited Use Criteria (Continued)

LU Code 551

For treatment-naive or treatment-experienced (1) adult patients with chronic hepatitis C (CHC) infection who meet all the following criteria:

(i) Treatment is prescribed by a hepatologist, gastroenterologist, infectious disease specialist or other prescriber experienced in treating chronic hepatitis C;

(ii) Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, or 6;

(iii) Two Laboratory confirmed quantitative HCV RNA values taken at least 6 months apart as demonstration of chronicity of infection. One level must be within the last 6 months while the first level may be at the time of the initial diagnosis.

Exclusion criteria:

- Patients with genotype 1 who have relapsed but are treatment experienced on both an NS3/4A protease inhibitor and an NS5A inhibitor
- For use in combination with other hepatitis C antiviral agents
- Patients with decompensated cirrhosis or severe hepatic impairment (Child-Pugh C)

Retreatment is not funded. Retreatment for re-infection in patients who have received an adequate prior course of Maviret will be considered on a case-by-case basis through the Exceptional Access Program.

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Treatment regimens for Maviret: **(Revisions are in bold)**

I. Treatment-naive genotype 3 with compensated cirrhosis.

Approved duration: 12 weeks

II. Treatment-experienced, cirrhotic genotype 1, 2, 4, 5, or 6 who have failed peginterferon/ribavirin and/or sofosbuvir ONLY.

Approved duration: 12 weeks

III**.** Treatment-experienced genotype 1 non-cirrhotic or compensated cirrhosis who have failed an NS3/4A protease inhibitor (2) but are NS5A inhibitor naive

Approved duration: 12 weeks

Notes:

(1) Treatment-experienced definitions vary by the genotype being treated. Health care professionals are advised to refer to the Maviret product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

(2) NS3/4A PIs include simeprevir, boceprevir, and telepravir.

(3) NS5A inhibitors include daclatasvir and ledipasvir.

LU Authorization Period: 12 weeks

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Revision of Limited Use Criteria (Continued)

Please Note:

LU Code 552 remains unchanged.

LU Code 550 is now applicable for adult patients with CHC infection with treatment-naive genotype 1, 2, 4, 5 or 6 with compensated cirrhosis meeting clinical criteria, with LU Authorization Period of 8 weeks. For clarity, LU Code 551 remains applicable for adult patients with CHC infection with treatment-naive genotype 3 with compensated cirrhosis meeting clinical criteria, and the LU Authorization Period for LU Code 551 remains 12 weeks.

Please note that transition RFU/LU Code 279 will be activated to transition CHC patients with treatment-naive genotype 1, 2, 4, 5, or 6 with compensated cirrhosis who initiated Maviret funding via LU Code 551 prior to the July 2020 formulary update. This transition LU code may be submitted for a claim for a period of 3 months after the change. It is expected that after 3 months all patients with a prescription for Maviret to have the correct LU Code and meet the revised clinical criteria. The transition code will be effective for 3 months and deactivated with the October 2020 formulary update.

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Transition from Exceptional Access Program to Limited Use

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
00363812	Buscopan	10mg	Tab	HYOSCINE BUTYLBROMIDE	SAC	0.3552

Reason For Use Code and Clinical Criteria

Code 481

For the management of patients receiving palliative care*.

LU Authorization Period: 1 year

Note: * The patient must have a progressive life-limiting illness and require this medication for palliative purposes.

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Temporary Benefits

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
09858122	PTU	50mg	Tab	PROPYLTHIOURACIL	PHB	0.3900
09858120	Timo-Stulln	0.5% w/v	Oph Sol	TIMOLOL MALEATE	PHS	1.2145/mL
09858119	Salbuhaler	100mcg/Metered Dose	Inh-200 Dose Pk	SALBUTAMOL SULFATE	SDZ	5.0000

Drug Benefit Price (DBP) Changes

To view the DBP changes by DIN/PIN, the ministry has posted an Excel file with the details of the listing changes for download and review (Edition 43: Summary of Changes – Drug Benefit Price Changes – July 31, 2020). It is accessible from the ministry's website: http://www.health.gov.on.ca/en/pro/programs/drugs/edition_43.aspx.