Ministry of Health and Long-Term Care

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – February 2019

Effective February 28, 2019

Drug Programs Policy and Strategy Branch
Drugs and Devices Division
Ministry of Health and Long-Term Care

Visit Formulary Downloads: Edition 43

Ontario

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New Single Source Product

DIN/PIN	Brand Name	Strength	Dosage Form	Generic Name	Mfr	DBP
02467550	Maviret	100mg & 40mg	Tab	GLECAPREVIR & PIBRENTASVIR	ABV	238.0952

Reason For Use Code and Clinical Criteria

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, or infectious disease specialist (or other physician 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 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:

I. Treatment-naive, non-cirrhotic genotype 1, 2, 3, 4, 5, or 6.
Approved duration: 8 weeks

II. 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.

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, or infectious disease specialist (or other physician 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.

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New Single Source Product (Continued)

Exclusion criteria:

- Patients with genotype 1 who have relapsed but are treatment experienced on both 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.

Treatment regimens for Maviret:

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

Code 552

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, or infectious disease specialist (or other physician experienced in treating a patient with chronic hepatitis C);

(ii) Laboratory confirmed hepatitis C genotype 1 or 3;

(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 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.

Treatment regimens for Maviret:

I. Treatment-experienced genotype 1 non-cirrhotic or compensated cirrhosis who have failed an NS5A inhibitor (3) but is NS3/4A protease inhibitor naive.
Approved duration: 16 weeks

II. Treatment-experienced genotype 3 non-cirrhotic or compensated cirrhosis who have failed peginterferon/ribavirin and/or sofosbuvir ONLY.
Approved duration: 16 weeks

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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.

New Multi-Source Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02426196	Mint-Hydrochlorothiazide	25mg	Tab	MIN	0.0157

(Interchangeable with HydroDIURIL)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02478889	Sandoz Morphine SR	100mg	SR Tab	SDZ	1.5395

(Interchangeable with MS Contin)

Therapeutic Note

Narcotic analgesics can produce dependence and may be abused. Physical dependence, psychological dependence and tolerance may develop. Prescribers are cautioned about ordering these drugs for patients with a history of either emotional disturbances or drug abuse, including alcohol.

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02479087	Jamp-Tenofovir	300mg	Tab	JPC	4.8884

(Interchangeable with Viread)

Code 517

Confirmed chronic Hepatitis B infection in persons with

- HBV DNA greater than or equal to 1000 IU/mL

AND

- ALT levels greater than ULN

OR

- Evidence of fibrosis

OR

- Documented evidence of cirrhosis

LU Authorization Period: 1 year

New Multi-Source Products (Continued)

Code 518

For patients with chronic Hepatitis B infection who have a contraindication, intolerance or inadequate response to one or more of the following: lamivudine, entecavir, adefovir or telbivudine.

LU Authorization Period: 1 year

Code 519

Patient is pregnant (2nd trimester or later) with HBV DNA greater than 1,000,000 IU/mL.

LU Authorization Period: 1 year

Code 520

Patients with chronic Hepatitis B infection currently receiving treatment with tenofovir and requires treatment continuation.

LU Authorization Period: 1 year

Code 521

Patients with chronic Hepatitis B infection who are scheduled to undergo chemotherapy or significant immunosuppressive treatment.

LU Authorization Period: 1 year

Code 522

For the treatment of HIV/AIDS, the prescriber must be approved for the Facilitated Access to HIV/AIDS Drug Products mechanism.

LU Authorization Period: 1 year

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02457059	Baclofen Injection	0.05mg/mL	Inj Sol-1mL Pk (Preservative-Free)	TEL	11.2500

(Interchangeable with Lioresal Intrathecal)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02457067	Baclofen Injection	0.5mg/mL	Inj Sol-20mL Pk (Preservative-Free)	TEL	177.2500

(Interchangeable with Lioresal Intrathecal)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02457075	Baclofen Injection	2mg/mL	Inj Sol-5mL Pk (Preservative-Free)	TEL	177.2500

(Interchangeable with Lioresal Intrathecal)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	Unit Price
02478897	Sandoz Morphine SR	200mg	SR Tab	SDZ	4.5738
09857617*	Sandoz Morphine SR	200mg	SR Tab	SDZ	4.5738

(Interchangeable with MS Contin)

* Palliative Care Facilitated Access PIN

Removal of Therapeutic Note

The following Therapeutic Note is removed from the Therapeutic Classification 40:28 DIURETICS.

Therapeutic Note

The Canadian Hypertension Society Consensus Conference recommends lower doses of diuretics for treatment of hypertension, particularly in the elderly, to avoid dose-related adverse effects. Hydrochlorothiazide, 25 to 50mg daily, or other diuretics in equivalent amounts are recommended.

Manufacturer Name Change

DIN/PIN	Brand Name	Strength	Dosage Form	Current Mfr	New Mfr
00363839	Buscopan	20mg/mL	Inj Sol	BOE	SAC

Drug Benefit Price (DBP) Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP/ Unit Price
02317966	Purg-Odan	3.5g & 12g & 10mg	Pd for Sol-12g Sachet	ODN	5.3900
02319977*	PMS-Oxycodone	5mg	Tab	PMS	0.1865
09857318**	PMS-Oxycodone	5mg	Tab	PMS	0.1865
02319985*	PMS-Oxycodone	10mg	Tab	PMS	0.2898
09857319**	PMS-Oxycodone	10mg	Tab	PMS	0.2898
02319993*	PMS-Oxycodone	20mg	Tab	PMS	0.4576
09857321**	PMS-Oxycodone	20mg	Tab	PMS	0.4576
02302799	Teva-Morphine SR	100mg	SR Tab	TEV	1.5395

* Off-Formulary Interchangeable (OFI) Product

** Palliative Care Facilitated Access Product

Discontinued Products

(Some products will remain on Formulary for six months to facilitate depletion of supply)

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02239757	Bactroban	2%	Cr	GSK
01916947	Bactroban	2%	Oint	GSK
02422468	Mar-Losartan	25mg	Tab	MAR
02422476	Mar-Losartan	50mg	Tab	MAR
02422484	Mar-Losartan	100mg	Tab	MAR
02396696*	Mylan-Fentanyl Matrix Patch	12mcg/hr	Trans Patch	MYL
02396718	Mylan-Fentanyl Matrix Patch	25mcg/hr	Trans Patch	MYL
02396726	Mylan-Fentanyl Matrix Patch	50mcg/hr	Trans Patch	MYL
02396734*	Mylan-Fentanyl Matrix Patch	75mcg/hr	Trans Patch	MYL
02396742*	Mylan-Fentanyl Matrix Patch	100mcg/hr	Trans Patch	MYL
02238604	PMS-Potassium Chloride	1.33mEq/mL	O/L	PMS
02264056	Teva-Ondansetron	4mg	Tab	TEV
02264064	Teva-Ondansetron	8mg	Tab	TEV

* Off-Formulary Interchangeable (OFI) Product

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
00630365	Pedialyte Regular	n/a	O/L	ABB
00981095	Pedialyte Flavored	n/a	O/L	ABB
01958100*	Cardura-1	1mg	Tab	AZC
01958097*	Cardura-2	2mg	Tab	AZC
01958119*	Cardura-4	4mg	Tab	AZC
02231353	Mylan-Cyclobenzaprine	10mg	Tab	MYL
02255987	Mylan-Meloxicam	7.5mg	Tab	MYL
02255995	Mylan-Meloxicam	15mg	Tab	MYL
02221799*	Frisium	10mg	Tab	OVA
02354926**	PMS-Repaglinide	0.5mg	Tab	PMS
02240693	Intron A	15mu/mL	18mu MD Pen Kit	SCH
02240694	Intron A	25mu/mL	30mu MD Pen Kit	SCH
02240695	Intron A	50mu/mL	60mu MD Pen Kit	SCH
02408082	Zoledronic Acid Injection	5mg/100mL	Inj Sol-100mL Pk (Preservative-Free)	TEV

* Remain on Formulary as Not-a-Benefit (NAB) to serve as a reference product in interchangeable group

** Off-Formulary Interchangeable (OFI) Product


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