Ontario

Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 43

Summary of Changes – June 2021

Effective June 30, 2021

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

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New Single Source Products

Generic Name: ENOXAPARIN SODIUM

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP
02506440	Noromby	20mg/0.2mL	Inj Sol-0.2mL Pref Syr (Preservative-Free)	JUN	3.5280/Pref Syr
02506459	Noromby	30mg/0.3mL	Inj Sol-0.3mL Pref Syr (Preservative-Free)	JUN	5.2920/Pref Syr
02506467	Noromby	40mg/0.4mL	Inj Sol-0.4mL Pref Syr (Preservative-Free)	JUN	7.0560/Pref Syr
02506475	Noromby	60mg/0.6mL	Inj Sol-0.6mL Pref Syr (Preservative-Free)	JUN	10.5840/Pref Syr
02506483	Noromby	80mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	JUN	14.1120/Pref Syr
02506491	Noromby	100mg/mL	Inj Sol-1mL Pref Syr (Preservative-Free)	JUN	17.6400/Pref Syr
02506505	Noromby HP	120mg/0.8mL	Inj Sol-0.8mL Pref Syr (Preservative-Free)	JUN	21.1680/Pref Syr
02506513	Noromby HP	150mg/mL	Inj Sol-1mL Pref Syr (Preservative-Free)	JUN	26.4600/Pref Syr

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
02399776	Levetiracetam Tablets	250mg	Tab	ACH	0.3210
02399784	Levetiracetam Tablets	500mg	Tab	ACH	0.3911
02399799	Levetiracetam Tablets	750mg	Tab	ACH	0.5416

(Interchangeable with Keppra – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02505363	AG-Ursodiol	250mg	Tab	ANG	0.3818

(Interchangeable with Urso – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02505371	AG-Ursodiol	500mg	Tab	ANG	0.7242

(Interchangeable with Urso DS – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02495066	Jamp Imatinib	100mg	Tab	JPC	5.2079
02495074	Jamp Imatinib	400mg	Tab	JPC	20.8314

(Interchangeable with Gleevec – GB)

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02502429	Jamp Prasugrel	10mg	Tab	JPC	1.6680

(Interchangeable with Effient)

Reason For Use Code and Clinical Criteria

Code 449

In combination with ASA for patients with:

ST-elevated myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) who have not received antiplatelet therapy prior to arrival in the catheterization lab.

OR

Acute coronary syndrome who failed on optimal clopidogrel and ASA therapy as defined by definite stent thrombosis (see note 1), or recurrent STEMI, or NSTEMI or UA after prior revascularization via PCI.

Treatment must be initiated in hospital. Funding approval is for up to 1 year.

Notes:

1. Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5mm of the stent OR is a visible thrombus within the stent OR is within 5mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours. Definite stent thrombosis must be confirmed by angiography or by pathologic evidence of acute thrombosis.
2. As per the product monograph, prasugrel is contraindicated in patients with a known history of transient ischemic attack or stroke; those with active pathological bleeding such as gastrointestinal bleeding or intracranial hemorrhage; and those with severe hepatic impairment (Child-Pugh Class C).
3. As per the product monograph, prasugrel is not recommended in patients greater than or equal to 75 years of age because of the increased risk of fatal and intracranial bleeding; or those with body weight less than 60kg because of increased risk of major bleeding due to an increase in exposure to the active metabolite of prasugrel.

LU Authorization Period: 1 year

New Multi-Source Products (Continued)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02433702	Priva-Fluconazole	150mg	Cap	PHP	3.9424

(Interchangeable with Diflucan-150 – LU)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	DBP
02506688	Aripiprazole	2mg	Tab	SAI	0.8092
02506718	Aripiprazole	5mg	Tab	SAI	0.9046
02506726	Aripiprazole	10mg	Tab	SAI	1.0754
02506734	Aripiprazole	15mg	Tab	SAI	1.2692
02506750	Aripiprazole	20mg	Tab	SAI	1.0017
02506785	Aripiprazole	30mg	Tab	SAI	1.0017

(Interchangeable with Abilify – GB)

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02492490	AG-Rizatriptan ODT	10mg	Orally Disintegrating Tab	ANG	11.1150

(Interchangeable with Maxalt RPD)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02514737	Reddy-Dasatinib	20mg	Tab	DRR	32.8823
02514745	Reddy-Dasatinib	50mg	Tab	DRR	66.1782
02514753	Reddy-Dasatinib	70mg	Tab	DRR	72.9336
02514761	Reddy-Dasatinib	80mg	Tab	DRR	117.3255
02514788	Reddy-Dasatinib	100mg	Tab	DRR	132.2670
02514796	Reddy-Dasatinib	140mg	Tab	DRR	141.8806

(Interchangeable with Sprycel)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02511266	Eletriptan	20mg	Tab	SAI	10.0850
02511274	Eletriptan	40mg	Tab	SAI	10.0850

(Interchangeable with Relpax)

DIN/PIN	Product Name	Strength	Dosage Form	Mfr	Unit Cost
02488507	Sandoz Pirfenidone Tablets	267mg	Tab	SDZ	6.7120
02488515	Sandoz Pirfenidone Tablets	801mg	Tab	SDZ	20.1360

(Interchangeable with Esbriet)

Transition from Limited Use to General Benefit

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02241093	Temodal	5mg	Cap	SCH
02441160	Act Temozolomide	5mg	Cap	ACV
02443473	Taro-Temozolomide	5mg	Cap	TAR
02241094	Temodal	20mg	Cap	SCH
02395274	Co Temozolomide	20mg	Cap	COB
02443481	Taro-Temozolomide	20mg	Cap	TAR
02241095	Temodal	100mg	Cap	SCH
02395282	Co Temozolomide	100mg	Cap	COB
02443511	Taro-Temozolomide	100mg	Cap	TAR
02312794	Temodal	140mg	Cap	SCH
02395290	Co Temozolomide	140mg	Cap	COB
02443538	Taro-Temozolomide	140mg	Cap	TAR
02241096	Temodal	250mg	Cap	SCH
02395312	Co Temozolomide	250mg	Cap	COB
02443554	Taro-Temozolomide	250mg	Cap	TAR
02237671	Neoral	10mg	Cap	NOV
02150689	Neoral	25mg	Cap	NOV
02247073	Sandoz Cyclosporine	25mg	Cap	SDZ
02150662	Neoral	50mg	Cap	NOV
02247074	Sandoz Cyclosporine	50mg	Cap	SDZ
02150670	Neoral	100mg	Cap	NOV
02242821	Sandoz Cyclosporine	100mg	Cap	SDZ
02150697	Neoral	100mg/mL	O/L	NOV

Revisions of Limited Use Criteria

Revisions are in bold

Code 482 (Harvoni - DIN 02432226)

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; AND

(ii) Laboratory confirmed hepatitis C genotype 1; AND

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;

OR

One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

Treatment regimens:

- Treatment-naive, non-cirrhotic, recent quantitative hepatitis C viral load less than 6 M IU/mL

Approved duration: 8 weeks

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

LU Authorization Period: 8 Weeks

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

Code 483

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; AND

(ii) Laboratory confirmed hepatitis C genotype 1; AND

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;

OR

One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

Treatment regimens:

I. Treatment-naive, without cirrhosis, viral load greater than or equal to 6 M IU/mL; or treatment-naive with cirrhosis; or treatment-experienced without cirrhosis

Approved duration: 12 weeks

II. Treatment-naive or treatment-experienced with decompensated cirrhosis (2)

Approved regimen: 12 weeks in combination with ribavirin (Ibavyr)

III. Treatment-naive or treatment-experienced liver transplant recipients without cirrhosis or with compensated cirrhosis (2)

Approved regimen: 12 weeks in combination with ribavirin (Ibavyr)

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

LU Authorization Period: 12 Weeks.

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

Code 484

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; AND

(ii) Laboratory confirmed hepatitis C genotype 1; AND

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;

OR

One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

Treatment regimen:

- Treatment-experienced, cirrhotic:

  Approved duration: 24 weeks

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

LU Authorization Period: 24 Weeks.

NOTE:

1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.

2. Compensated cirrhosis (Child-Turcotte-Pugh A [i.e. Scores 5 to 6]) and decompensated cirrhosis (Child-Turcotte-Pugh B or C [i.e. Score 7 or above]) may be considered.

3. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

Code 485 (Sovaldi - DIN 02418355)

In combination with ribavirin (Ibavyr) 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; AND

(ii) Laboratory confirmed hepatitis C genotype 2; AND

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;
OR
One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

For patients who meet the eligibility criteria for sofosbuvir (Sovaldi), clinicians are encouraged to choose sofosbuvir/velpatasvir (Epclusa) as the preferred therapeutic option over sofosbuvir with ribavirin regimens for treatment of genotype 2 or 3 patients only. This recommendation is based on evidence that Epclusa offers advantages in some patient populations, including potentially higher SVR rates and a shorter course of therapy for genotype 3 infections.

Treatment regimens for sofosbuvir (Sovaldi) for genotype 2:

- Treatment-naive or treatment-experienced genotype 2

Approved regimen: 12 weeks in combination with ribavirin (Ibavyr)

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

LU Authorization Period: 12 Weeks.

Code 486 - Discontinued

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

Code 487

In combination with ribavirin (Ibavyr) 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; AND

(ii) Laboratory confirmed hepatitis C genotype 3; AND

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;

OR

One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

For patients who meet the eligibility criteria for sofosbuvir (Sovaldi), clinicians are encouraged to choose sofosbuvir/velpatasvir (Epclusa) as the preferred therapeutic option over sofosbuvir with ribavirin regimens for treatment of genotype 2 or 3 patients only. This recommendation is based on evidence that Epclusa offers advantages in some patient populations, including potentially higher SVR rates and a shorter course of therapy for genotype 3 infections.

Treatment regimens for sofosbuvir (Sovaldi) for genotype 3:

- Treatment-naive or treatment-experienced without cirrhosis, or with compensated cirrhosis (2), or with decompensated cirrhosis (2), or post-liver transplant

  Approved regimen: 24 weeks in combination with ribavirin (Ibavyr).

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

LU Authorization Period: 24 Weeks.

NOTE**:**

1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.

2. Compensated cirrhosis (Child-Turcotte-Pugh A [i.e. Score 5 to 6]) and decompensated cirrhosis (Child-Turcotte-Pugh B or C [i.e. Score 7 or above]) may be considered.

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

3. Combination therapy with Zepatier (elbasvir/grazoprevir) will not be considered for funding.

4. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

Code 488 (Epclusa - DIN 02456370)

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; AND

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

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;
OR
One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

Treatment regimens for Epclusa (sofosbuvir-velpatasvir):

I. Treatment-naive or treatment-experienced (1) non-cirrhotic or compensated cirrhosis (2)

Approved duration: 12 weeks

II. Treatment-naive or treatment-experienced patients with decompensated cirrhosis (2)

Approved regimen: 12 weeks in combination with ribavirin (Ibavyr)

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

LU Authorization Period: 12 Weeks.

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

NOTE:

1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.

2. Compensated cirrhosis (Child-Turcotte-Pugh A [i.e. Scores 5 to 6]) and decompensated cirrhosis (Child-Turcotte-Pugh B or C [i.e. Score 7 or above]) may be considered.

3. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

Code 524 (Vosevi - DIN 02467542)

For 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; AND

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

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;

OR

One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

Treatment regimen for Vosevi (sofosbuvir-velpatasvir-voxilaprevir):

Treatment-experienced, non-cirrhotic or compensated cirrhosis (2)

Approved duration: 12 weeks

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

LU Authorization Period: 12 Weeks.

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

NOTE:

1. Treatment-experienced are those who failed prior therapy with a HCV regimen containing:

i. NS5A inhibitor* for genotype 1, 2, 3, 4, 5, or 6; OR

ii. Sofosbuvir (Sovaldi) without an NS5A inhibitor for genotype 1, 2, 3, or 4

***NS5A inhibitors include: daclatasvir (Daklinza), elbasvir (as part of Zepatier), ledipasvir (as part of Harvoni), ombitasvir (as part of Holkira Pak), velpatasvir (as part of Epclusa), pibrentasvir (as part of Maviret)**

2. Compensated cirrhosis (Child-Turcotte-Pugh A [i.e. Scores 5 to 6]) may be considered.

3. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the drug product, including use in special populations.

Code 489 (Zepatier - DIN 02451131)

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; AND

(ii) Laboratory confirmed hepatitis C genotype 1 or genotype 4; AND

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;
OR
One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

Treatment regimens for Zepatier (elbasvir-grazoprevir) for genotype 1:

I. Treatment-naive with or without compensated cirrhosis (2)

Approved duration: 12 weeks

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

Note: As approved by Health Canada, 8 weeks may be considered in treatment-naive genotype 1b patients without significant fibrosis or cirrhosis as determined by liver biopsy (i.e., Metavir F0-F2) or by non-invasive tests.

II. Treatment-experienced genotype 1b patients and genotype 1a relapsers, with or without compensated cirrhosis (2)

Approved duration: 12 weeks

Treatment regimens for Zepatier (elbasvir-grazoprevir) for genotype 4:

I. Treatment-naive patients, treatment-experienced relapsers, with or without compensated cirrhosis (2)

Approved duration: 12 weeks

Retreatment for failure or re-infection in patients who have received an adequate prior course of direct-acting antiviral will be considered on a case-by-case basis through the Exceptional Access Program.

LU Authorization Period: 12 Weeks.

Code 490

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; AND

(ii) Laboratory confirmed hepatitis C genotype 1 or genotype 4 AND

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;
OR
One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

Treatment-experienced genotype 1a or genotype 4 who have had on-treatment virologic failures (3)

Approved regimen: 16 weeks in combination with ribavirin (Ibavyr)

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

LU Authorization Period: 16 Weeks.

NOTE:

1. Treatment-experienced for patients with genotype 1 is defined as patients who have been previously treated with a pegylated interferon + ribavirin regimen or a protease inhibitor + pegylated interferon + ribavirin regimen and have not experienced adequate response.

Treatment-experienced for patients with genotype 4 is defined as patients who have been previously treated with a pegylated interferon + ribavirin regimen and have not experienced adequate response.

2. Treatment may be considered for patients with compensated cirrhosis (Child-Turcotte-Pugh A [i.e. Score 5 to 6])

3. On-treatment virologic failures are patients who have had a null response, partial response, virologic breakthrough or rebound, or intolerance to prior treatment.

4. Combination therapy with Sovaldi (sofosbuvir) will not be considered for funding for any genotypes.

5. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the selected drug, including use in special populations.

Code 550 (Maviret - DIN 02467550)

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;

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;
OR
One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

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.

Treatment regimens for Maviret:

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

Approved duration: 8 weeks

II. Treatment-naive genotype 1, 2, 3, 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

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

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, 4, 5, or 6;

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;

OR

One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

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.

Treatment regimens for Maviret:

I. Treatment-experienced, genotype 1, 2, 4, 5, or 6 with compensated cirrhosis who have failed peginterferon/ribavirin and/or sofosbuvir ONLY.

Approved duration: 12 weeks

II. 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

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

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.

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, infectious disease specialist or other prescriber experienced in treating chronic hepatitis C;

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

(iii) Established chronicity of HCV infection either by two laboratory confirmed quantitative HCV RNA values taken at least 6 months apart;

OR

One recent laboratory confirmed quantitative HCV RNA within the past 6 months and clinical features establishing a duration of HCV infection longer than 6 months (e.g. presence of fibrosis, presence of non-liver manifestations of HCV, prolonged ALT elevation greater than 6 months without another cause, HCV antibody positivity greater than 6 months), or risk factors for HCV acquisition greater than 6 months (e.g. injection drug use).

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.

Revisions and Discontinuation of Limited Use Criteria (Continued)

Ontario

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

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: 16 Weeks.

Product Brand Name Change

DIN/PIN	Current Brand Name	New Brand Name	Strength	Dosage Form	MFR
02470632	Triamcinolone Hexacetonide Inj. Susp.	Trispan	20mg/mL	1mL-Amp Pk	MDX

Drug Benefit Price (DBP) Changes

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr	DBP/Unit Price
00015229	Aventyl	10mg	Cap	AAP	0.2819
00015237	Aventyl	25mg	Cap	AAP	0.5697
00860689	Clorazepate	3.75mg	Cap	AAP	0.1687
00860700	Clorazepate	7.5mg	Cap	AAP	0.2200
00860697	Clorazepate	15mg	Cap	AAP	0.4405
02249510	Midamor	5mg	Tab	AAP	0.3103
00511528	Mogadon	5mg	Tab	AAP	0.1718
00511536	Mogadon	10mg	Tab	AAP	0.2571
00604453	Restoril	15mg	Cap	AAP	0.2317
00604461	Restoril	30mg	Cap	AAP	0.2804
00024325	Sinequan	10mg	Cap	AAP	0.3835
00024333	Sinequan	25mg	Cap	AAP	0.4705
00024341	Sinequan	50mg	Cap	AAP	0.8728
00271373	Winpred	1mg	Tab	AAP	0.1201
02245246	Apo-Indapamide	1.25mg	Tab	APX	0.1490
00755877	Apo-Pindol	5mg	Tab	APX	0.3699
00755885	Apo-Pindol	10mg	Tab	APX	0.6315
02240067	Mylan-Indapamide	1.25mg	Tab	MYL	0.1490
02413167	Sandoz Travoprost	0.004%	Oph Sol-5mL Pk	SDZ	28.7600
00869007	Teva-Pindolol	5mg	Tab	TEV	0.3699
00869015	Teva-Pindolol	10mg	Tab	TEV	0.6315

Discontinued Products

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

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
02393247	Co Telmisartan	40mg	Tab	COB
02421550	Zoledronic Acid for Injection	4mg/5mL	Inj Sol-5mL Pk (Preservative-Free)	HOS
02238674	Intron A	6,000,000U/mL	Inj Sol-ready to use 3mL Vial Pk	MEK
02238675	Intron A	10,000,000U/mL	Inj Sol-ready to use 1mg Vial Pk	MEK
09854053	Intron A	10,000,000U/mL	Inj Sol-ready to use 2.5mL Vial Pk	MEK
00010200	Propyl-Thyracil	50mg	Tab	PAL
00010219	Propyl-Thyracil	100mg	Tab	PAL

Delisted Products

DIN/PIN	Brand Name	Strength	Dosage Form	Mfr
09857639*	Accel-Sevelamer	800mg	Tab	ACC
00545023	Apo-Bisacodyl	5mg	Ent Tab	APX
02244324	Apo-Cyclosporine Oral Solution	100mg/mL	O/L	APX
02415739	Apo-Travoprost Z	0.004%	Oph Sol-5mL Pk	APX
02230020	Viokase	16800 & 70000 & 70000 USP U/0.7g	Pd-114g Pk	BFI
02279320	Invirase	500mg	Tab	HLR
00599875	Mucillium		Oral Pd	PMS
09857504	Teva-Travoprost Z Ophthalmic Solution	0.004%	Oph Sol-2.5mL Pk	TEV
02412063	Teva-Travoprost Z Ophthalmic Solution	0.004%	Oph Sol-5mL Pk	TEV

*PIN is replaced by DIN 02461501, interchangeable with Renvela DIN 02354586