Ontario Drug Benefit Formulary/Comparative Drug Index

Edition 42

Summary of Changes – February 2017

Effective February 28, 2017

Drug Programs Policy and Strategy Branch

Ontario Public Drug Programs

Ministry of Health and Long-Term Care

Ontario

Table of Contents

New Single Source Products

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02452294	Sunvepra 100mg Cap	ASUNAPREVIR	BQU	38.6905

Reason For Use Code and Clinical Criteria

Code: 491
For use as combination treatment with daclatasivir (Daklinza) for treatment naïve 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 CHC); AND

(ii) Laboratory confirmed hepatitis C infection with genotype 1b; AND

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

(iv) Fibrosis stage (2) of F2 or greater (Metavir scale or equivalent)

OR Fibrosis stage less than F2 in those with at least one of the following:

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g: non-alcoholic steatohepatitis)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

Treatment regimens for asunaprevir (Sunvepra) for genotype 1b:

Treatment-naive or treatment-experienced adult patients, with or without compensated cirrhosis (5)

Approval regimen: 24 weeks in combination with daclatasvir (Daklinza)

New Single Source Products (Cont'd...)

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

Notes:

1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Acceptable methods for the measurement of fibrosis score include liver biopsy, transient elastography (FibroScan), fibrotest, serum biomarker panels (such as AST-to-Platelet Ratio Index (APRI) or Fibrosis-4 (FIB-4) score) either alone or in combination.
3. Extra-hepatic manifestation include but not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, Lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 to include patients with glomerular filtration rate less than 60 mL/min/1.73 square metre for greater than or equal to 3 months.
5. Treatment may be considered for patients with compensated cirrhosis (Child-Turcotte-Pugh A) (Score 5 to 6)
6. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the selected drugs, including use in special populations.

New Single Source Products (Cont'd...)

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02444747	Daklinza 30mg Tab	DACLATASVIR	BQU	428.5714
02444755	Daklinza 60mg Tab	DACLATASVIR	BQU	428.5714

Reason For Use Code and Clinical Criteria

Code: 492

For use as combination therapy with asunaprevir (Sunvepra) for treatment naïve 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 CHC); AND

(ii) Laboratory confirmed hepatitis C infection with genotype 1b; AND

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

(iv) Fibrosis stage (2) of F2 or greater (Metavir scale or equivalent)

OR Fibrosis stage less than F2 in those with at least one of the following;

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g.non-alcoholic steatohepatitis)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

Treatment regimens for daclatasvir (Daklinza) for genotype 1b:

Treatment-naive or treatment-experienced adult patients, with or without compensated cirrhosis (5)

Approval regimen: 24 weeks in combination with asunaprevir (Sunvepra)

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.

New Single Source Products (Cont'd...)

LU Authorization Period: 24 Weeks

Code: 493

For use as combination therapy with sofosbuvir (Sovaldi) for treatment naïve or treatment experienced (1) adult patients with chronic hepatitis C 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); AND

(ii) Laboratory confirmed hepatitis C infection with genotype 3; AND

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

(iv) Fibrosis stage (2) of F2 or greater (Metavir scale or equivalent)

OR Fibrosis stage less than F2 in those with at least one of the following;

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Post organ transplant (may include liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by the National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

Treatment regimens for daclatasvir (Daklinza) for genotype 3:

I. Treatment-naïve or treatment-experienced without cirrhosis

Approved regimen: 12 weeks in combination with sofosbuvir (Sovaldi)

II. Treatment-naive or treatment-experienced with compensated cirrhosis (5); or decompensated cirrhosis (5); or post-liver transplant.

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

New Single Source Products (Cont'd...)

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

Notes:

1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Acceptable methods for the measurement of fibrosis score include liver biopsy, transient elastography (FibroScan), fibrotest, serum biomarker panels (such as AST-to-Platelet Ratio Index (APRI) or Fibrosis-4 (FIB-4) score) either alone or in combination.
3. Extra-hepatic manifestation include but not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, Lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 to include patients with glomerular filtration rate (GFR) less than 60 mL/min/1.73 square metre for greater than or equal to 3 months.
5. Treatment may be considered for patients with 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])
6. Health care professionals are advised to refer to the product monograph and prescribing guidelines for appropriate use of the selected drugs, including use in special populations.

New Single Source Products (Cont'd...)

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02451131	Zepatier 50mg & 100mg Tab	ELBASVIR & GRAZOPREVIR	MEK	717.8571

Reason For Use Code and Clinical Criteria

Code: 489
For treatment naïve 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 CHC); AND

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

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent); OR Fibrosis stage less than F2 in those with at least one of the following:

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Extra-hepatic (3) manifestations

D. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

E. Diabetes receiving treatment with anti-diabetic drugs

F. Woman of childbearing age planning pregnancy within the next 12 months

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

I. Treatment-naïve with or without compensated cirrhosis (5)

Approved duration: 12 weeks

Note: As approved by Health Canada, **8 weeks** may be considered in treatment-naïve 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 (5)

Approved duration: 12 weeks

New Single Source Products (Cont'd...)

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

Treatment-naïve patients, treatment-experienced relapsers, with or without compensated cirrhosis (5)

Approved duration: 12 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: 12 Weeks

Code: 490

For treatment naïve 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 CHC); AND

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

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent); OR Fibrosis stage less than F2 in those with at least one of the following:

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Extra-hepatic (3) manifestations

D. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

E. Diabetes receiving treatment with anti-diabetic drugs

F. Woman of childbearing age planning pregnancy within the next 12 months

Treatment-experienced genotype 1a or genotype 4 who have had on-treatment virologic failures (6)

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

New Single Source Products (Cont'd...)

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

Notes:

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. Acceptable methods for the measurement of fibrosis score include liver biopsy, transient elastography (FibroScan), fibrotest, serum biomarker panels (such as AST-to-Platelet Ratio Index (APRI) or Fibrosis-4 (FIB-4) score) either alone or in combination.
3. Extra-hepatic manifestation include but not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, Lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 to include patients with glomerular filtration rate less than 60 mL/min/1.73 square metre for greater than or equal to 3 months.
5. Treatment may be considered for patients with compensated cirrhosis (Child-Turcotte-Pugh A) [i.e. Score 5-6]).
6. On-treatment virologic failures are patients who have had a null response, partial response, virologic breakthrough or rebound, or intolerance to prior treatment.
7. Combination therapy with sofosbuvir (Sovaldi) will not be considered for funding for any genotypes.
8. 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.

New Single Source Products (Cont'd...)

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02432226	Harvoni 90mg & 400mg Tab	LEDIPASVIR & SOFOSBUVIR	GIL	797.6190

Reason For Use Code and Clinical Criteria

Code: 482

For treatment naïve 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 CHC); AND

(ii) Laboratory confirmed hepatitis C genotype 1; AND

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent) OR Fibrosis stage less than F2 and at least one of the following;

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

Treatment regimens:

Treatment-naïve, 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

New Single Source Products (Cont'd...)

Code: 483

For treatment naïve 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 CHC); AND

(ii) Laboratory confirmed hepatitis C genotype 1; AND

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent) OR Fibrosis stage less than F2 and at least one of the following;

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

Treatment regimens:

I. Treatment-naïve, non-cirrhotic or cirrhotic, viral load greater than or equal to 6 M IU/mL; or treatment-experienced non-cirrhotic
Approved duration: 12 weeks

II. Treatment-naïve or treatment-experienced with decompensated cirrhosis (5)

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

III. Treatment-naïve or treatment-experienced liver transplant recipients without cirrhosis or with compensated cirrhosis (5)

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

New Single Source Products (Cont'd...)

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: 484

For treatment naïve 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 CHC); AND

(ii) Laboratory confirmed hepatitis C genotype 1; AND

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent) OR Fibrosis stage less than F2 and at least one of the following;

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

Treatment regimens:

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

New Single Source Products (Cont'd...)

Notes:

1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Acceptable methods for measuring fibrosis score include liver biopsy, transient elastography (FibroScan), fibrotest, serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score).
3. Extra-hepatic manifestation may include: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, Lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 to include patients with glomerular filtration rate less than 60 mL/min/1.73 square metre for greater than or equal to 3 months.
5. 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.
6. 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.

New Single Source Products (Cont'd...)

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02439212	Ibavyr 200mg Tab	RIBAVIRIN	PEN	7.2500
02425890	Ibavyr 400mg Tab	RIBAVIRIN	PEN	14.5000
02425904	Ibavyr 600mg Tab	RIBAVIRIN	PEN	21.7500

Reason For Use Code and Clinical Criteria

Code: 494
For use within a Ministry-approved and funded combination therapy regimen for the treatment of chronic hepatitis C according to specific eligibility criteria.

The regimen for the use of ribavirin must comply with the Ontario Drug Benefit Program's criteria for funding of the hepatitis C regimen in which it is being administered and use of ribavirin outside of an approved hepatitis C funded regimen will not be reimbursed.

Note: The requesting physician is a hepatologist, gastroenterologist or an infectious disease specialist, or otherwise experienced in treating hepatitis C.

LU Authorization Period: Up to a Maximum of 24 Weeks

New Single Source Products (Cont'd...)

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02418355	Sovaldi 400mg Tab	SOFOSBUVIR	GIL	654.7619

Reason For Use Code and Clinical Criteria

Code: 485

In combination with ribavirin (Ibavyr) for treatment naïve 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 CHC); AND

(ii) Laboratory confirmed hepatitis C genotype 2; AND

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent)

OR

Fibrosis stage less than F2 and at least one of the following

A. Co-infection with HIV or hepatitis B virus
B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)
C. Post organ transplant (liver and/or non-liver transplant)
D. Extra-hepatic (3) manifestations
E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative
F. Diabetes receiving treatment with anti-diabetic drugs
G. Woman of childbearing age planning pregnancy within the next 12 months

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

New Single Source Products (Cont'd...)

Treatment regimens for sofosbuvir (Sovaldi) for genotype 2:

Treatment-naïve 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

In combination with ribavirin (Ibavyr) or daclatasvir (Daklinza) or both for treatment naïve 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 CHC); AND

ii. Laboratory confirmed hepatitis C genotype 3; AND

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; AND

iv. Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent) OR Fibrosis stage less than F2 and at least one of the following

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

For patients who meet the eligibility criteria for sofosbuvir (Sovaldi), clinicians are encouraged to choose sofosbuvir/velpatasvir (Epclusa) or sofosbuvir in combination with daclatasvir (Daklinza) as one of the preferred therapeutic options over sofosbuvir with

New Single Source Products (Cont'd...)

ribavirin regimens for treatment genotype 2 or 3 patients only. This recommendation is based on evidence that Epclusa or Daklinza in combination with sofosbuvir 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

Approved regimens:
12 weeks in combination with daclatasvir (Daklinza)

Treatment-naive or treatment-experienced with compensated cirrhosis (5); or decompensated cirrhosis (5); or post-liver transplant

Approved regimen:
12 weeks in combination with daclatasvir (Daklinza) and 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: 487

In combination with ribavirin (Ibavyr) for treatment naïve 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 CHC); AND

(ii) Laboratory confirmed hepatitis C genotype 3; AND

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent)

OR Fibrosis stage less than F2 and at least one of the following

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

New Single Source Products (Cont'd...)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

For patients who meet the eligibility criteria for sofosbuvir (Sovaldi), clinicians are encouraged to choose sofosbuvir/velpatasvir (Epclusa) or sofosbuvir in combination with daclatasvir (Daklinza) as one of the preferred therapeutic options over sofosbuvir with ribavirin regimens for treatment genotype 2 or 3 patients only. This recommendation is based on evidence that Epclusa or Daklinza in combination with sofosbuvir 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 (5), or with decompensated cirrhosis (5), 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

Notes:

1. Treatment-experienced are those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Acceptable methods for measuring fibrosis score include liver biopsy, transient elastography (FibroScan), fibrotest, serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score).
3. Extra-hepatic manifestation may include: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, Lichen planus, and glomerulonephritis.

New Single Source Products (Cont'd...)

4. Chronic kidney disease stage 3, 4 or 5 to include patients with glomerular filtration rate less than 60 mL/min/1.73 square metre for greater than or equal to 3 months.
5. 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.
6. Combination therapy with Zepatier (elbasvir/grazoprevir) will not be considered for funding.
7. 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.

New Single Source Products (Cont'd...)

DIN/PIN	PRODUCT NAME,STRENGTH & DOSAGE FORM	GENERIC NAME	MFR	DBP
02456370	Epclusa 400mg & 100mg Tab	SOFOSBUVIR & VELPATASVIR	GIL	714.2857

Reason For Use Code and Clinical Criteria

Code: 488

For treatment naïve 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); AND

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

(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; AND

(iv) Fibrosis (2) stage of F2 or greater (Metavir scale or equivalent); OR Fibrosis stage less than F2 in those with at least one of the following:

A. Co-infection with HIV or hepatitis B virus

B. Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)

C. Post organ transplant (liver and/or non-liver transplant)

D. Extra-hepatic (3) manifestations

E. Chronic kidney disease (4) stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative

F. Diabetes receiving treatment with anti-diabetic drugs

G. Woman of childbearing age planning pregnancy within the next 12 months

H. Treatment regimens for Epclusa (sofosbuvir-velpatasvir):

I. Treatment-naïve or treatment-experienced, non-cirrhotic or compensated cirrhosis (5)

Approved duration: 12 weeks

II. Treatment-naïve or treatment-experienced patients with decompensated cirrhosis (5)

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.

New Single Source Products (Cont'd...)

LU Authorization Period: 12 Weeks

Notes:

1. Treatment-experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
2. Acceptable methods for the measurement of fibrosis score include liver biopsy, transient elastography (FibroScan), fibrotest, serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.
3. Extra-hepatic manifestation include but not limited to: symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma, porphyria cutanea tarda, Lichen planus, and glomerulonephritis.
4. Chronic kidney disease stage 3, 4 or 5 to include patients with glomerular filtration rate less than 60 mL/min/1.73 square metre for greater than or equal to 3 months.
5. 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.
6. 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.

New Multi-Source Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02457288	Sandoz Amphetamine XR	5mg	ER Cap	SDZ	0.5372
02457296	Sandoz Amphetamine XR	10mg	ER Cap	SDZ	0.6105
02457318	Sandoz Amphetamine XR	15mg	ER Cap	SDZ	0.6838
02457326	Sandoz Amphetamine XR	20mg	ER Cap	SDZ	0.7572
02457334	Sandoz Amphetamine XR	25mg	ER Cap	SDZ	0.8305
02457342	Sandoz Amphetamine XR	30mg	ER Cap	SDZ	0.9038

(Interchangeable with Adderall XR)

Therapeutic Note(s)

Notes: Patients > 6 years of age diagnosed with ADHD according to DSM-IV criteria and where symptoms are not due to other medical conditions which affect concentration, and who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet the following:

1) Patients who demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; AND

2) Prescribed by or in consultation with a specialist in pediatric psychiatry, pediatrics or a general practitioner with expertise in ADHD; AND

3) Have been tried on methylphenidate immediate release (IR) or methylphenidate slow release (SR) or Dexedrine IR or Dexedrine SR (Spansules), and have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers, or societal barriers.

Administrative barriers include:

- inability of a school to dose the child at lunch;
- the school lunch hour does not coincide with the dosing schedule;
- poor compliance with noon or afternoon doses;
- the patient is unable to swallow tablets.

Societal barriers include:

- the patient or patient's caregiver(s) has(have) a history of substance abuse or diversion of listed immediate-release alternatives;
- the patient or patient's caregiver(s) is/are at risk of substance abuse or diversion of listed immediate-release alternatives.

New Multi-Source Products (Cont'd...)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02457954	Mint-Levocarb	100mg & 10mg	Tab	MIN	0.1479
02457962	Mint-Levocarb	100mg & 25mg	Tab	MIN	0.2209
02457970	Mint-Levocarb	250mg & 25mg	Tab	MIN	0.2466

(Interchangeable with Sinemet)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02425009	Contingency One	1.5mg	Tab-1 Tab Pk	MYL	8.6000

(Interchangeable with Plan B)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP
02457814	Med-Moxifloxacin	400mg	Tab	GMP	1.5230

(Interchangeable Avelox)

Reason For Use Code and Clinical Criteria

For the treatment of patients with:

Code 337
CAP with co-morbidity: Community acquired pneumonia with co-morbid illnesses or failure to first-line therapy.

LU Authorization Period: 1 year.

Code 338
COPD with risk: Acute bacterial exacerbation of chronic obstructive pulmonary disease (COPD) with risk factors*; bronchiectasis.

*Risk factors include: poor pulmonary lung function (FEV1 below 50% predicted level), age over 65 years, co-morbid medical illness (congestive heart failure, diabetes, chronic renal failure, chronic liver disease), chronic corticosteroid use, malnutrition, prolonged duration of disease or 4 or more exacerbations per year.

LU Authorization Period: 1 year.

New Multi-Source Products (Cont'd...)

Code 339
Step-Down: Step-down therapy after parenteral therapy or hospital / emergency department discharge.

LU Authorization Period: 1 year.

Code 977
Exceptional cases of allergy or intolerance to all other appropriate therapies.

LU Authorization Period: 1 year.

New Off-Formulary Interchangeable (OFI) Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02434547	Mylan-Cinacalcet	60mg	Tab	MYL	18.5900
02434555	Mylan-Cinacalcet	90mg	Tab	MYL	27.0517

(Interchangeable with Sensipar)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02287064	Cyclobenzaprine	10mg	Tab	SAI	0.3765

(Interchangeable with Flexeril)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02403366	Apo-Rosiglitazone	2mg	Tab	APX	1.1692
02403374	Apo-Rosiglitazone	4mg	Tab	APX	1.8346
02403382	Apo-Rosiglitazone	8mg	Tab	APX	2.6235

(Interchangeable with Avandia)

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	UNIT COST
02436175	PMS-Zolpidem ODT	5mg	SL Tab	PMS	1.1827
02436183	PMS-Zolpidem ODT	10mg	SL Tab	PMS	1.1883

(Interchangeable with Sublinox)

Products Status Change from Palliative Care Facilitated Access Progam to Limited Use

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP (per mL)
00780626	Phenytoin Sodium Injection USP	50mg/mL	Inj Sol (Preservative Free)	SDZ	6.0785
02185431	Metoclopramide HCL Injection	5mg/mL	Inj Sol (Preservative Free)	SDZ	3.3925
00527033	Furosemide Injection USP	10mg/mL	Inj Sol (Preservative Free)	SDZ	0.8650
00392537	Dimenhydrinate Inj 50mg USP	50mg/mL	Inj Sol (With Preservative)	SDZ	1.3800
00399728	Diazepam Injection USP	5mg/mL	Inj Sol (Preservative Free)	SDZ	1.6415
02243278	Lorazepam Injection USP	4mg/mL	Inj Sol (With Preservative)	SDZ	21.2000

Reason For Use Code and Clinical Criteria

Code: 481
For the management of patients receiving palliative care*

LU Authorization Period: 12 months.

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

PIN*	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
09857240	Sandoz Diazepam	5mg/mL	Inj 2mL Pk	SDZ
09857207	Sandoz Dimenhydrinate	50mg/mL	Inj-5mL Pk	SDZ
09857208	Sandoz Furosemide	10mg/mL	Inj Sol-2mL Pk	SDZ
09857216	Sandoz Lorazepam	4mg/mL	Inj-1mL Pk	SDZ
09857224	Sandoz Metoclopramide	10mg/2mL	Inj-2mL Pk	SDZ
09857235	Sandoz Phenytoin	50mg/mL	Inj-2mL Pk	SDZ

*The use of these Palliative Care Facilitated Access (PCFA) Product Identification Numbers (PIN) is discontinued as these products are transitioned to the Formulary as Limited Use drugs.

Product Manufacturer Name Change

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	CURRENT MFR	NEW MFR
02290308	Cyestra-35	2mg & 0.035mg	Tab-21 Pk	PMS	PAL

Product Brand and Manufacturer Name Changes

DIN/PIN	CURRENT BRAND NAME	CURRENT MFR	NEW BRAND NAME	NEW MFR	STRENGTH	DOSAGE FORM
02413620	Vpi-Baclofen Intrathecal	VPI	Val-Baclofen Intrathecal	VAL	0.05mg/mL	Inj Sol-1mL Pk (Preservative-Free)
02413639	Vpi-Baclofen Intrathecal	VPI	Val-Baclofen Intrathecal	VAL	0.5mg/mL	Inj Sol-20mL Pk (Preservative-Free)
02413647	Vpi-Baclofen Intrathecal	VPI	Val-Baclofen Intrathecal	VAL	2mg/mL	Inj Sol-5mL Pk (Preservative-Free)

Drug Benefit Price (DBP) / Unit Price Changes

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR	DBP / UNIT PRICE
02439239	Act Amphetamine XR	5mg	ER Cap	ACV	0.5372
02439247	Act Amphetamine XR	10mg	ER Cap	ACV	0.6105
02439255	Act Amphetamine XR	15mg	ER Cap	ACV	0.6838
02439263	Act Amphetamine XR	20mg	ER Cap	ACV	0.7572
02439271	Act Amphetamine XR	25mg	ER Cap	ACV	0.8305
02439298	Act Amphetamine XR	30mg	ER Cap	ACV	0.9038
02195933	Apo-Levocarb	100mg & 10mg	Tab	APX	0.1479
02195941	Apo-Levocarb	100mg & 25mg	Tab	APX	0.2209
02195968	Apo-Levocarb	250mg & 25mg	Tab	APX	0.2466
00022799	Zarontin	250mg	Cap	ERF	0.5000
02423413*	Mylan-Rivastigmine Patch 5	9mg/5 Sq Cm	Trans Patch	MYL	3.9773
02423421*	Mylan-Rivastigmine Patch 10	18mg/10 Sq Cm	Trans Patch	MYL	3.9773
02244494	Novo-Levocarbidopa	100mg & 10mg	Tab	NOP	0.1479
02244495	Novo-Levocarbidopa	100mg & 25mg	Tab	NOP	0.2209
02244496	Novo-Levocarbidopa	250mg & 25mg	Tab	NOP	0.2466

*Off Formulary Interchangeable Products

Discontinued Products

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

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
00022802	Celontin	300mg	Cap	ERF
00024430	Navane	2mg	Cap	ERF
00024457	Navane	10mg	Cap	ERF
00638692	Procan SR	250mg	LA Tab	ERF
00638676	Procan SR	500mg	LA Tab	ERF
00638684	Procan SR	750mg	LA Tab	ERF
02181215	Cotazym ECS 4	4000 & 11000 & 11000 USP Units	Ent Microsph Cap	ORG

Delisted Products

DIN/PIN	BRAND NAME	STRENGTH	DOSAGE FORM	MFR
00023949*	Thyroid	30mg	Tab	ERF
00023957*	Thyroid	60mg	Tab	ERF
00023965*	Thyroid	125mg	Tab	ERF
02312298	Novo-Raloxifene	60mg	Tab	NOP
00782327**	Andriol	40mg	Cap	ORG
02247021	Ratio-Aclavulanate	875mg & 125mg	Tab	RPH
01934139	Ratio-Indomethacin	100mg	Sup	RPH
00860808	Ratio-Salbutamol Respirator Sol	5mg/mL	Inh Sol-10mL Pk	RPH

*Existing patients on the drug (a prescription filled for one of the 3 strengths between September 1, 2016 and February 27, 2017) will be provided with a transition period of 6 months (until August 31, 2017) to consult their physicians and determine a suitable alternative therapy. Pharmacists are encouraged to plan accordingly to prevent interruptions in drug therapy for their patients and counsel affected patients appropriately. For any questions, please contact the ODB Help Desk.

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


Ontario