Hepatitis C Medications
Effective 04/01/2020

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview:

For MassHealth members:
GENERIC Harvoni™ (ledipasvir/sofosbuvir 90mg/400mg) is a preferred combination agent HCV medication for Genotype 1, 4, 5 or 6
GENERIC Epclusa® (sofosbuvir/velpatasvir) is a preferred combination agent HCV medication for *GENOTYPES 1-6*
Mavyret™ is a preferred combination agent HCV medication for Genotypes 1-6
Current prior authorizations will be grandfathered for the life of the prior authorization
****NOTE: Generic Harvoni (ledipasvir/sofosbuvir) is available and is preferred for all MassHealth members =/>18 years of age. BRAND NAME Harvoni may be dispensed to members ages 3 to < 18 ONLY per Mass Health.**

AllWays Health Partners will continue to review non-preferred products on a case by case basis and cover when medically necessary.

All Hepatitis C medications are specialty products; dispensing is available only when obtained from any AllWays Health Partners contracted specialty pharmacy including CVS Caremark Specialty Pharmacy.

NOTE: FDA has received reports that the use of Mavyret, Zepatier, or Vosevi to treat chronic Hepatitis C in patients with moderate to severe liver impairment has resulted in rare cases of worsening liver function or liver failure. Mavyret and Zepatier should not be prescribed in patients with any history of prior hepatic decompensation. Vosevi is indicated for patients who have previously failed certain other

Hepatitis C Virus treatments and is not recommended in patients with any history of hepatic decompensation unless the benefits outweigh the risk of liver injury, liver failure or death.

AllWays Health Partners will continue to review non-preferred products on a case by case basis and cover when medically necessary.

Coverage Guidelines

Approval will be granted if the member meets all following criteria and documentation has been submitted:

Approvable Diagnosis

- Chronic hepatitis C (CHC) infection

- Member is new to AllWays Health Partners and has already been started and stabilized on a regimen of hepatitis C medication(s) as part of an appropriate treatment regimen (e.g. genotype, combination therapy, dose, treatment duration, etc.) for chronic hepatitis C infection

OR

- Member has a diagnosis of chronic hepatitis C (CHC) infection **AND**
- Member has a detectable HCV RNA viral load drawn from within the last 6 months **AND**
- Member has documented liver disease **AND**
- Member has documentation of stage of hepatic fibrosis through one of the following:
  - Liver biopsy confirming a Metavir stage
  - Transient elastography (FibroScan®) score
  - Fibrotest (such as FibroSureTM) score
  - AST to Platelet Ratio Index (APRI) score
  - Severe extra hepatic manifestations/symptoms

OR

- Member has failed previous treatment with an NS5A inhibitor OR regimen of sofosbuvir without an NS5A inhibitor **AND**
- Member has a diagnosis of chronic hepatitis C (CHC) infection **AND**
- Member has a detectable HCV RNA viral load drawn from within the last 6 months **AND**
- Member has documented liver disease **AND**
- Member has documentation of stage of hepatic fibrosis through one of the following:

o Liver biopsy confirming a Metavir stage
o Transient elastography (FibroScan®) score
o Fibrotest (such as FibroSureTM) score
o AST to Platelet Ratio Index (APRI) score
o Severe extra hepatic manifestations/symptoms

AND all of the following:

- Member has demonstrated understanding of the proposed treatment plan and has displayed the ability to adhere to medications and clinical appointments **AND**
- The requested dose and duration of therapy are consistent with published label indications **and/or contraindication(s)** for each medication and the AASLD published treatment guidelines, management in Tables 1 through 3.

- Provider will submit HCV RNA viral load 12 weeks (SVR12) after completion of therapy to assess virologic cure.
- For therapies exceeding 12 weeks, provider will submit HCV RNA viral load at week 4 of treatment. Repeat HCV RNA should be drawn at 6 weeks if viral load is detectable at week 4.
- All other requests will be reviewed on a case-by-case basis consistent with approved FDA labeling and/or recognized treatment guidelines.

Limitations:

Hepatitis Antiviral Agents – Combination Agents			MassHealth
Drug Generic Name	**Drug Brand Name**	**PA Status**	
dasabuvir / ombitasvir / paritaprevir / ritonavir extended-release	Viekira XR	PA	MassHealth Preferred agents noted as PD ALL require prior authorization.
elbasvir / grazoprevir	Zepatier	PA	
glecaprevir / pibrentasvir	Mavyret PD	PA	
ledipasvir / sofosbuvir PD (generic 90mg/400mg) **	Harvoni	PA	
ombitasvir / paritaprevir / ritonavir	Technivie	PA	
ombitasvir / paritaprevir / ritonavir / dasabuvir	Viekira Pak	PA	
sofosbuvir / velpatasvir PD (generic)	Epclusa	PA	
sofosbuvir / velpatasvir / voxilaprevir	Vosevi	PA	

**** Ledipasvir/sofosbuvir (Harvoni) :** . Eight weeks of treatment can be considered for treatment-naïve adults with HCV genotype 1 without cirrhosis and baseline HCV viral load <6 million IU/mL.

MassHealth Preferred Hepatitis C Product Reference Table:

HCV GT	Treatment History	Cirrhosis Status	Preferred Regimen(s) (listed in alphabetical order)[1]
GT1	Naïve	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks • ledipasvir/sofosbuvir(90mg/400mg) x 8 weeks (if viral load <6 million IU/mL) • Mavyret x 8 weeks

HCV GT	Treatment History	Cirrhosis Status	Preferred Regimen(s) (listed in alphabetical order)[1]
	Naïve	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks • Mavyret x 8 weeks
	Experienced (PEG/RBV)	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks • Mavyret x 12 weeks
	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks
	Experienced (PI+PEG/RBV)	Non-cirrhotic or cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks
	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2] • Mavyret x 16 weeks • Vosevi x 12 weeks (GT 1a)
	Experienced (SOF+PEG/RBV or SOF+RBV)	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2] • Mavyret x 16 weeks (GT 1a) • Vosevi x 12 weeks (GT 1a)
	Experienced (SOF+SMV)	Non-cirrhotic or cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2] • Mavyret x 12 weeks (GT 1a) • Vosevi x 12 weeks (GT 1a)
	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 16 weeks (no prior PI) • Vosevi x 12 weeks
GT2	Naïve or experienced (PEG/RBV)	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks • Mavyret x 8 weeks
	Naïve or experienced (PEG/RBV)	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks
	Experienced (SOF+RBV)	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks[2] • Mavyret x 8 weeks

HCV GT	Treatment History	Cirrhosis Status	Preferred Regimen(s) (listed in alphabetical order)[1]
	Experienced (SOF+RBV)	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks[2]
	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks
GT3	Naïve	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks • Mavyret x 8 weeks
	Naïve	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks (plus RBV[2] if Y93H substitution is present)
	Experienced (PEG/RBV)	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks (plus RBV[2] if Y93H substitution is present)
	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir +RBV x 12 weeks[2]
	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 16 weeks • Vosevi x 12 weeks
	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks (plus RBV[2] if cirrhosis is present)
GT4, 5, or 6	Naïve or experienced (PEG/RBV)	Non-cirrhotic	• sofosbuvir/velpatasvir x 12 weeks • Mavyret x 8 weeks
	Naïve or experienced (PEG/RBV)	Cirrhotic (CTP A)	• sofosbuvir/velpatasvir x 12 weeks
	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic	• Mavyret x 8 weeks • Vosevi x 12 weeks[2]
	Experienced (SOF+PEG/RBV or SOF+RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • Vosevi x 12 weeks[2]
	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks
Unique Populations			

HCV GT	Treatment History	Cirrhosis Status	Preferred Regimen(s) (listed in alphabetical order)[1]
GT 1, 4, 5, or 6, age ≥ 12 and <18 years old	Naïve or experienced (PEG/RBV)	Non-cirrhotic or cirrhotic (CTP A)	• ledipasvir/sofosbuvir(90mg/400mg) x 12 weeks (24 weeks if GT1, treatment-experienced [PEG/RBV] with cirrhosis [CTP A])
GT 2 or 3, age ≥12 and <18 years old	Naïve or experienced (PEG/RBV)	Non-cirrhotic or cirrhotic (CTP A)	• Sovaldi+RBV x 12 weeks (GT 2) • Sovaldi+RBV x 24 weeks (GT 3)
GT1-6, eGFR<30 mL	DAA-naïve or DAA-experienced	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 8, 12, or 16 weeks (based on genotype, presence of cirrhosis, and prior treatment experience)
GT 1-6, CTP B or C	Naïve or experienced (PEG/RBV±PI)	Cirrhotic (CTP B or C)	• sofosbuvir/velpatasvir +RBV x 12 weeks
GT 1-6, CTP B or C	Experienced (SOF or NS5A-based regimen)	Cirrhotic (CTP B or C)	• sofosbuvir/velpatasvir +RBV x 24 weeks[2]
GT 1, 4, 5, or 6, liver transplant	Naïve or experienced (PEG/RBV±PI)	Non-cirrhotic or cirrhotic (CTP A, B, or C)	• ledipasvir/sofosbuvir (90mg/400mg)+RBV x 12 weeks[2]
GT 2 or 3, liver transplant	Naïve or experienced (no prior NS5A inhibitor)	Non-cirrhotic	• Mavyret x 12 weeks[2]
GT 2 or 3, liver transplant	Naïve or experienced (PEG/RBV)	Cirrhotic (CTP A)	• Daklinza+Sovaldi+RBV x 12 weeks[2]
GT 2 or 3, liver transplant	Naïve or experienced (PEG/RBV±PI)	Cirrhotic (CTP B or C)	• sofosbuvir/velpatasvir +RBV x 12 weeks[2]
GT 1 or 4, kidney transplant	Naïve or experienced (PEG/RBV±PI)	Non-cirrhotic or cirrhotic (CTP A)	• ledipasvir/sofosbuvir(90mg/400mg) x 12 weeks[2]
GT 2, 3, 5, or 6, kidney transplant	Naïve or experienced (no prior NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 12 weeks[2]

CTP=Child Turcotte Pugh, DAA=direct-acting antiviral, eGFR=estimated glomerular filtration rate, GT=genotype

Notes

- Non-responders (or null responders) are defined as those who experienced less than a 2 log decline in viral load during a previous 12 week treatment course (viral load was never

undetectable). Partial responders experienced greater viral load suppression than non- responders, but viral load was never undetectable during treatment. These individuals have lower re-treatment success.

- Relapsers are defined as those who achieved undetectable HCV RNA blood levels during previous treatment who relapsed after treatment cessation. Relapsers should be treated as if they are naïve to therapy. These individuals tend to do well with re-treatment.
- For patients who are currently taking an antacid, H2 antagonist, or proton pump inhibitor and require a sofosbuvir/velpatasvir - or ledipasvir/sofosbuvir -containing regimen, AllWays Health Partners requires documentation of how this drug interaction will be managed.

References

1. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America.
2. Recommendations for testing, managing and treating Hepatitis C. (AASLD) (IDSA) Revised September 21, 2017. Guideline available at: http://www.hcvguidelines.org/.

Review History

11/20/2019 – Reviewed; updates to MH PD
11/18/2020 – Reviewed; separated out Comm/Exch vs. MH; no clinical changes

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.