Hepatitis C Treatment Criteria

HealthPartners

Coverage Criteria – Commercial Products

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Table of Contents

Preferred Regimens by Genotype & Condition 2

Coverage Criteria 3

- Hepatitis C Treatment Exclusion Criteria 3
- Case-by-Case Reviews 3
- Preferred Regimens: Sofosbuvir/velpatasvir, Ledipasvir/sofosbuvir x 8 weeks, Mavyret, Vosevi 4
  - Required Inclusion Criteria 4
  - Preferred Regimens 5
- Non-Preferred Regimens: Ledipasvir/sofosbuvir x 12 and 24 weeks, Sovaldi, VieKira/VieKira XR Pak, Zepatier 6
  - Required Inclusion Criteria 6
  - Preferred Regimens 7

Preferred Regimens by Genotype & Condition

Treatment-naïve Regimens

Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1	Ledipasvir/sofosbuvir* x 8 weeks Mavyretx x 8 weeks Sofosbuvir/velpatasvir* x 12 weeks	Mavyret x 8 weeks Sofosbuvir/velpatasvir x 12 weeks
2	Sofosbuvir/velpatasvir x 12 weeks Mavyret x 8 weeks	Mavyret x 8 weeks Sofosbuvir/velpatasvir x 12 weeks
3	Sofosbuvir/velpatasvir x 12 weeks Mavyret x 8 weeks	Mavyret x 8 weeks Sofosbuvir/velpatasvir x 12 weeks
4	Sofosbuvir/velpatasvir x 12 weeks Mavyret x 8 weeks	Mavyret x 8 weeks Sofosbuvir/velpatasvir x 12 weeks
5	Sofosbuvir/velpatasvir x 12 weeks Mavyret x 8 weeks	Mavyret x 8 weeks Sofosbuvir/velpatasvir x 12 weeks
6	Sofosbuvir/velpatasvir x 12 weeks Mavyret x 8 weeks	Mavyret x 8 weeks Sofosbuvir/velpatasvir x 12 weeks

*** Harvoni and Epclusa require use of the generic formulations unless patient has documentation of an allergic reaction to the generic products. Exceptions will be made for dosage forms in which a generic is unavailable and the dose is medically necessary (example: Epclusa 150-37.5mg pellet for children weighing less than 17kg).**

Treatment-experienced Regimens

Genotype	Previous Treatment Experience	Treatment Regimen	
		No Cirrhosis	**Compensated Cirrhosis (Child-Pugh A)**
1	An NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor	Mavyret x 16 weeks	Mavyret x 16 weeks
	An NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor	Mavyret x 12 weeks	Mavyret x 12 weeks
	An NS5A inhibitor with prior treatment with an NS3/4A protease inhibitor	Vosevi x 12 weeks	Vosevi x 12 weeks
	PRS[1]	Mavyret x 8 weeks	Mavyret x 12 weeks
2	NS5A inhibitor	Vosevi x 12 weeks	Vosevi x 12 weeks
	PRS[1]	Mavyret x 8 weeks	Mavyret x 12 weeks
3	NS5A inhibitor	Vosevi x 12 weeks	Vosevi x 12 weeks
	PRS[1]	Mavyret x 16 weeks	Mavyret x 16 weeks
4	NS5A inhibitor	Vosevi x 12 weeks	Vosevi x 12 weeks
	PRS[1]	Mavyret x 8 weeks	Mavyret x 12 weeks
5	NS5A inhibitor	Vosevi x 12 weeks	Vosevi x 12 weeks
	PRS[1]	Mavyret x 8 weeks	Mavyret x 12 weeks
6	NS5A inhibitor	Vosevi x 12 weeks	Vosevi x 12 weeks
	PRS[1]	Mavyret x 8 weeks	Mavyret x 12 weeks

[1]PRS = Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.
NS5A inhibitor: Includes, but is not limited to, prior regimens containing ledipasvir, or daclatasvir.
NS3/4A protease inhibitor: Includes, but is not limited to, prior regimens containing simeprevir, boceprevir, or telaprevir.

Coverage Criteria

Hepatitis C Treatment Exclusion Criteria

Patients with the following conditions are not eligible for hepatitis C treatment:

1. Currently pregnant or planning on becoming pregnant in the next six months; or,
2. Severe end organ disease and is not eligible for solid organ transplant; or,
3. Clinically-significant illness or any other major medical disorder that may interfere with a patient's ability to complete a course of treatment; or,
4. Patients who in the professional judgment of the primary treating clinician would not achieve a long term clinical benefit from HCV treatment (e.g., patients with multisystem organ failure, receiving palliative care or are enrolled in hospice, the presence of significant pulmonary or cardiac disease, and malignancy outside of the liver not meeting oncologic criteria for cure); or,
5. Decompensated liver disease with Child-Pugh-Turcotte > 10 or MELD > 20; or,
6. MELD ≤ 20 and one of the following:
   A. Cardiopulmonary disease that cannot be correct and is a prohibitive risk for surgery; or,
   B. Malignancy outside of the liver not meeting oncologic criteria for cure; or,
   C. Hepatocellular carcinoma with metastatic spread or not listed for liver transplant; or,
   D. Intrahepatic cholangiocarcinoma; or,
   E. Hemangiosarcoma.

Case-by-Case Reviews

Requests for combinations of any marketed direct acting antiviral medications, and all other requests not meeting the criteria specified below will be reviewed on a case by case basis.

Preferred Regimens: Sofosbuvir/velpatasvir, Ledipasvir/sofosbuvir x 8 weeks, Mavyret, Vosevi

Required Inclusion Criteria

Requests must meet the following criteria prior to approval:

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patient's age is consistent with FDA approved labeling, meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
   A. Laboratory confirmed diagnosis of chronic hepatitis C virus; and,
   B. Laboratory confirmed genotyping of hepatitis C virus; and,
   C. Pretreatment viral load within one year of regimen start date; and,
3. The patient is motivated, has been counseled and is likely to complete treatment as prescribed. Potential impediments to successful treatment must be addressed in the treatment notes prior to initiating treatment and submitted with the authorization request. An attestation has been completed by both the provider AND patient. The care team should also ensure that the patient has evidence of health insurance coverage and evidence of a stable living arrangement for the duration of treatment.
4. Providers are encouraged to counsel patients with a history of alcohol use to be abstinent from alcohol use for six months or longer prior to requesting treatment approval.
   A. For retreatment requests, patients with a history of alcohol use must be abstinent from alcohol use for six months or longer prior to requesting treatment approval. Exceptions will be considered for patients who have abstained from alcohol for at least three months if they are:
      1) Receiving clinically appropriate chemical dependency treatment (e.g., recovery program, counseling, under the care of an addiction specialist (medical record documentation required); AND,
      2) The patient attests that they agree to abstain from alcohol use during treatment.
5. Providers are encouraged to counsel patients with a history of intravenous drug use to be abstinent from intravenous drugs for six months or longer prior to requesting treatment approval.
   A. For retreatment requests, patients with a history of intravenous drug use must be abstinent from Intravenous drugs for six months or longer. Exceptions will be considered for patients who have abstained from intravenous drugs for at least three months if they are:
      1) Receiving clinically appropriate chemical dependency treatment (e.g., recovery program, counseling, under the care of an addiction specialist (medical record documentation required); AND,
      2) The provider attests that the patient has abstained from use for three months and has a negative urine tox screen within thirty days of starting therapy (medical record documentation required).
6. The drug regimen meets ALL the following criteria as evidenced by written documentation from the medical record:
   A. An FDA-approved regimen is prescribed; and,
   B. Use is not in combination with any other direct acting antiviral (e.g., Sofosbuvir/velpatasvir, Ledipasvir/sofosbuvir, Zepatier®, Mavyret®, Vosevi®, or VieKira/VieKira XR Pak®); and,
   C. A plan for managing any drug interactions is indicated.

7. The proposed start date will be provided at the time of the prior authorization request. Drug supplies will not be dispensed until one week before the start date.
8. Virologic response will be submitted at 12 weeks after completion of treatment.
9. Patients prescribed Harvoni are required to use the authorized generic formulation unless the patient has a documented allergic reaction to the generic product or is a pediatric patient weighing between 17 and 35 kg and prescribed the 45mg/200 mg Harvoni formulation.
10. Patients prescribed Epclusa are required to use the authorized generic formulation unless the patient has a documented allergic reaction to the generic product. Exceptions will be made for dosage forms in which a generic is unavailable and the dose is medically necessary (example: Epclusa 150-37.5mg pellet for children weighing less than 17kg).
11. Harvoni 45/200 mg or Sovaldi 200 mg will be restricted for treatment naïve or experienced pediatric patients weighing between 17-35 kg.
12. Prescribing is consistent with preferred regimens below unless there are documented contraindications to, or inability to tolerate **all** preferred regimens:

Preferred Regimens

Treatment-Naïve:

1. Genotype 1 – Ledipasvir/sofosbuvir x 8 weeks, Mavyret, and Sofosbuvir/velpatasvir regimensare the preferredtreatmentsfor patientswith genotype 1 virus.
2. Genotype 2 through 6 - Sofosbuvir/velpatasvir and Mavyret® regimens are the preferred treatments for patients with genotype 2 through 6 virus.

Treatment-Experienced, with Previous DAA(Direct-Acting Antiviral) Failure:

1. Genotype 1, retreatment for patients who failed on either NS5A or NS3/4A PI – Mavyret® is the preferred treatment.
2. Genotype 1, retreatment for patients who failed on both NS5A and NS3/4A PI – Vosevi® is the preferred treatment.
3. Genotype 2 through 6 - Vosevi is the preferred treatment.

Non-Preferred Regimens: Ledipasvir/sofosbuvir x 12 and 24 weeks, Sovaldi, VieKira/VieKira XR Pak, Zepatier

Ledipasvir/sofosbuvir x 8 weeks, Sofosbuvir/velpatasvir, and Mavyret® regimens are the preferred treatments. Therefore, documented clinical inappropriateness or inability to tolerate Ledipasvir/sofosbuvir 8 weeks and Sofosbuvir/velpatasvir and Mavyret® will be required prior to approval of non-preferred regimens.

Required Inclusion Criteria

Requests must meet the following criteria prior to approval:

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patient's age is consistent with FDA approved labeling, meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
   A. Laboratory confirmed diagnosis of chronic hepatitis C virus; and,
   B. Laboratory confirmed genotyping of hepatitis C virus; and,
   C. Pretreatment viral load within one year of regimen start date; and,
3. The patient is motivated, has been counseled and is likely to complete treatment as prescribed. Potential impediments to successful treatment must be addressed in the treatment notes prior to initiating treatment and submitted with the authorization request. An attestation has been completed by both the provider AND patient. The care team should also ensure that the patient has evidence of health insurance coverage and evidence of a stable living arrangement for the duration of treatment.
4. Patients with a history of alcohol use must be abstinent from alcohol use for six months or longer prior to requesting treatment approval. Exceptions will be considered for patients who have abstained from alcohol for at least three months if they are:
   A. Receiving clinically appropriate chemical dependency treatment (e.g., recovery program, counseling, under the care of an addiction specialist (medical record documentation required); AND,
   B. The patient attests that they agree to abstain from alcohol use during treatment.
5. Patients with a history of intravenous drug use must be abstinent from intravenous drugs for six months or longer. Exceptions will be considered for patients who have abstained from intravenous drugs for at least three months if they are:
   A. Receiving clinically appropriate chemical dependency treatment (e.g., recovery program, counseling, under the care of an addiction specialist (medical record documentation required); AND,
   B. The provider attests that the patient has abstained from use for three months and has a negative urine tox screen within thirty days of starting therapy (medical record documentation required).
6. The drug regimen meets ALL the following criteria as evidenced by written documentation from the medical record:
   A. An FDA-approved regimen is prescribed; and,
   B. Use is not in combination with any other direct acting antiviral (e.g., Sofosbuvir/velpatasvir, Ledipasvir/sofosbuvir, Zepatier®, Mavyret®, Vosevi®, or VieKira/VieKira XR Pak®); and,
   C. A plan for managing any drug interactions is indicated.
7. The proposed start date will be provided at the time of the prior authorization request. Drug supplies will not be dispensed until one week before the start date.
8. Virologic response will be submitted at 12 weeks after completion of treatment.

9. Patients prescribed Harvoni are required to use the authorized generic formulation unless the patient has a documented allergic reaction to the generic product or is a pediatric patient weighing between 17 and 35 kg and prescribed the 45mg/200 mg Harvoni formulation.
10. Patients prescribed Epclusa are required to use the authorized generic formulation unless the patient has a documented allergic reaction to the generic product. Exceptions will be made for dosage forms in which a generic is unavailable and the dose is medically necessary (example: Epclusa 150-37.5mg pellet for children weighing less than 17kg).
11. Harvoni 45/200 mg or Sovaldi 200 mg will be restricted for treatment naïve or experienced pediatric patients weighing between 17-35 kg.
12. Prescribing is consistent with preferred regimens below unless there are documented contraindications to, or inability to tolerate all preferred regimens:

Preferred Regimens

Ledipasvir/sofosbuvir x12 and 24 weeks, Sovaldi, VieKira/VieKira XR Pak, and Zepatier® are non- preferred regimens. Therefore, documented clinical inappropriateness or inability to tolerate **all** preferred regimens will be required prior to approval. Preferred regimens include:

Treatment-Naïve:

1. Genotype 1 – Ledipasvir/sofosbuvir x 8 weeks, Mavyret, and Sofosbuvir/velpatasvir regimens are the preferred treatments for patients with genotype 1 virus.
2. Genotype 2 through 6 - Sofosbuvir/velpatasvir and Mavyret® regimens are the preferred treatments for
patients with genotype 2 through 6 virus.

Treatment-Experienced, with Previous DAA(Direct-Acting Antiviral) Failure:

1. Genotype 1, retreatment for patients who failed on either NS5A or NS3/4A PI – Mavyret® is the preferred treatment.
2. Genotype 1, retreatment for patients who failedon both NS5A and NS3/4A PI – Vosevi® is the preferred treatment.
3. Genotype 2 through 6 - Vosevi is the preferred treatment