



Hepatitis C Treatment Criteria

Coverage Criteria – Commercial Products

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Preferred Regimens by Genotype & Condition

Genotype	Preferred Harvoni/Epclusa Regimens		Preferred Zepatier Regimens	
1	Treatment-naïve without cirrhosis with HCV RNA less than 6M IU/mL	Harvoni x 8 weeks	Genotype 1a treatment naïve or PIFN/RBV-experienced without baseline NS5A polymorphisms with or without cirrhosis	Zepatier x 12 weeks
	Treatment-naïve without cirrhosis with HCV RNA greater than 6M IU/mL	Harvoni x 12 weeks	Genotype 1a treatment naïve or PIFN/RBV-experienced with baseline NS5A polymorphisms with or without cirrhosis	Zepatier + RBV x 16 weeks
	Treatment-naïve with cirrhosis	Harvoni x 12 weeks	Genotype 1b treatment naïve or PIFN/RBV-experienced with or without cirrhosis	Zepatier x 12 weeks
	Treatment-experienced without cirrhosis	Harvoni x 12 weeks (Add RBV if Incivek, Victrelis, Olysio, Sovaldi failure)	Genotype 1a or 1b PIFN/RBV/Protease inhibitor-experienced with or without cirrhosis	Zepatier + RBV x 12 weeks
	Treatment- experienced with cirrhosis	Harvoni +RBV x 12 weeks (Add RBV if Sovaldi failure)		
2	All	Epclusa x 12 weeks		
3	All	Epclusa x 12 weeks		
4	All	Harvoni x 12 weeks	Treatment-naive with or without cirrhosis	Zepatier x 12 weeks
			PIFN /RBV experienced with or without cirrhosis	Zepatier + RBV x 16 weeks
5	All	Harvoni x 12 weeks		
6	All	Harvoni x 12 weeks		

Abbreviations:

PIFN =Pegylated Interferon

RBV = Ribavirin

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 \leq 20 and one of the following:
 - A. Cardiopulmonary disease that cannot be corrected 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 use in prior direct acting antiviral failures, 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.

Definition of "Interferon Ineligible"

Interferon ineligible patients are defined as follows: (Requests must be supported with medical chart documentation.)

1. Previous intolerance to interferon; or,
2. Autoimmune hepatitis and other immune disorders; or,
3. Hypersensitivity to pegylated interferon or any of its components; or,
4. Decompensated hepatic disease; or,
5. Major uncontrolled depressive illness documented in the medical chart; or,
6. A baseline neutrophil count below 1500/mm³; or,
7. Baseline platelet count below 90,000/mm³; or,
8. Baseline hemoglobin below 10 g/dL; or,
9. A history of preexisting cardiac disease

Harvoni

Required Inclusion Criteria

Requests meeting all of the below criteria will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients ≥ 18 years of age meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
 - A. Laboratory confirmed diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6 virus; and,
 - B. 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., Epclusa®, Sovaldi®, Zepatier®, Daklinza®, Olysio®, Technivie®, 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.

Harvoni (continued)

Approval Durations

Harvoni® will be approved in patients meeting the above criteria as follows:

1. Genotype 1 – Harvoni® and Zepatier® regimens are the preferred treatments for patients with genotype 1 virus. Harvoni regimens will be approved as follows:
 - A. Non-cirrhotic, treatment naïve, and pretreatment HCV RNA <6 million IU/mL patients will be approved for 8 weeks total duration.
 - B. Cirrhotic patients (Metavir F4 or equivalent) who failed previous chronic hepatitis C treatment will be approved for 12 weeks in combination with ribavirin. Evidence of prior intolerance resulting in discontinuation (not dose reduction) of ribavirin will be required for approval of 24 week regimens without ribavirin.
 - C. All others will be approved for 12 weeks total duration.
2. Genotype 2 – Requests for Harvoni® will be reviewed on a case by case basis. Epclusa® regimens are the preferred treatments for patients with genotype 2 virus.
3. Genotype 3 – Requests for Harvoni® will be reviewed on a case by case basis. Epclusa® regimens are the preferred treatments for patients with genotype 3 virus.
4. Genotype 4 - Harvoni® and Zepatier® regimens are the preferred treatments for patients with genotype 4 virus. Harvoni regimens will be approved as follows:

For all patients, 12 weeks will be approved.
5. Genotypes 5 and 6 - Harvoni® regimens are the preferred treatments for patients with genotypes 5 and 6 virus.

For all patients, 12 weeks will be approved.

Epclusa

Required Inclusion Criteria

Requests meeting all of criteria below will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients \geq 18 years of age meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
 - A. Laboratory confirmed diagnosis of chronic hepatitis C virus types 2 and 3; and,
 - B. 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.
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.
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 direct acting antiviral agents (e.g., Harvoni[®], Zepatier[®], Sovaldi[®], Technivie[®], or VieKira/VieKira XR Pak[®]) and,
 - C. A plan for managing any drug interactions is indicated. Providers must avoid proton-pump inhibitors unless medically necessary, and follow acid-reducing medication instructions as indicated in the Epclusa package insert.
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.

Epclusa (continued)

Approval Durations

Epclusa® will be approved in patients meeting the above criteria as follows:

1. Genotype 1 – Requests for Epclusa® will be reviewed on a case by case basis. Harvoni® and Zepatier® regimens are the preferred treatments for patients with genotype 1 virus.
2. Genotypes 2 and 3 - Epclusa® regimens are the preferred treatments for patients with genotype 2 and 3 virus. Epclusa regimens will be approved as follows:
For all patients, 12 weeks will be approved.
3. Genotype 4 - Requests for Epclusa® will be reviewed on a case by case basis. Harvoni® and Zepatier® regimens are the preferred treatments for patients with genotype 4 virus.
4. Genotypes 5 and 6 - Requests for Epclusa® will be reviewed on a case by case basis. Harvoni® regimens are the preferred treatments for patients with genotypes 5 and 6 virus.

Sovaldi

Required Inclusion Criteria

Requests meeting all of criteria below will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients ≥ 18 years of age 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. 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 direct acting antiviral agents (e.g., Epclusa[®], Harvoni[®], Zepatier[®], , Technivie[®], or VieKira/VieKira XR Pak[®]) except when it is approved in combination with Daklinza[®] or Olysio[®] and in accordance with an FDA approved regimen 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.

Sovaldi (continued)

Approval Durations

Sovaldi® will be approved in patients meeting the above criteria as follows:

1. Genotype 1 – Requests for Sovaldi® will be reviewed on a case by case basis. Harvoni® and Zepatier® regimens are the preferred treatments for patients with genotype 1 virus.
2. Genotype 2 - Requests for Sovaldi® will be reviewed on a case by case basis. Epclusa® regimens are the preferred treatments for patients with genotype 2 virus.
3. Genotype 3 – Requests for Sovaldi® will be reviewed on a case by case basis. Epclusa® regimens are the preferred treatments for patients with genotype 3 virus.
4. Genotype 4 - Requests for Sovaldi® will be reviewed on a case by case basis. Harvoni® and Zepatier® regimens are the preferred treatments for patients with genotype 4 virus.
5. Genotypes 5 and 6 - Requests for Sovaldi® will be reviewed on a case by case basis. Harvoni® regimens are the preferred treatments for patients with genotypes 5 and 6 virus.

Zepatier

Required Inclusion Criteria

Requests meeting all of the below criteria will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients \geq 18 years of age meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
 - A. Laboratory confirmed diagnosis of chronic hepatitis C genotype 1 or 4; and,
 - B. Pretreatment NS5A polymorphism test; 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., Epclusa[®], Harvoni[®], Sovaldi[®], Daklinza[®], Olysio[®], Technivie[®], 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.

Zepatier (continued)

Approval Durations

Zepatier® will be approved in patients meeting the above criteria as follows:

1. Genotype 1 –Zepatier® and Harvoni® regimens are the preferred treatments for patients with genotype 1 virus. Zepatier® is the preferred agent for patients with renal failure. Zepatier® regimens will be approved as follows:
 - A. For genotype 1a treatment-naïve or PIFN/RBV experienced without baseline NS5A polymorphisms, 12 weeks will be approved.
 - B. For genotype 1a treatment-naïve or PIFN/RBV experienced with baseline NS5A polymorphisms, 16 weeks will be approved when used in combination with ribavirin.
 - C. For genotype 1b treatment-naïve or PIFN/RBV experienced, 12 weeks will be approved.
 - D. Genotype 1a or 1b PIFN/RBV/protease inhibitor experienced, 12 weeks will be approved when used with ribavirin.
2. Genotypes 2 and 3 – Zepatier® has not been studied in and will not be approved for treatment of genotypes 2 and 3 virus. Epclusa® regimens are the preferred treatments for patients with genotypes 2 and 3 virus
3. Genotype 4 - Zepatier® and Harvoni® regimens are the preferred treatments for patients with genotype 4 virus. Zepatier® is the preferred agent for patients with renal failure. Zepatier® regimens will be approved as follows:
 - A. For treatment-naïve patients, 12 weeks will be approved.
 - B. For ribavirin/interferon-experienced patients, 16 weeks will be approved when used in combination with ribavirin.
4. Genotypes 5 and 6 – Zepatier® has not been studied in and will not be approved for treatment of patients with genotype 5 or 6 virus. Harvoni® regimens are the preferred treatments for patients with genotypes 5 and 6 virus.

Daklinza

Epclusa® regimens are the preferred treatments for viral genotypes 2 and 3. Therefore, documented clinical inappropriateness or inability to tolerate Epclusa® will be required prior to Daklinza® approval.

Required Inclusion Criteria

Requests meeting all of criteria below will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients ≥ 18 years of age meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
 - A. Laboratory confirmed diagnosis of chronic hepatitis C genotype 3 virus; and,
 - B. 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 must be in combination with Sovaldi® but not with any other direct acting antiviral (e.g., Epclusa®, Harvoni®, Zepatier®, Olysio®, Technivie®, 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.

Daklinza (continued)

Approval Durations

Daklinza® will be approved as follows in patients with genotype 3 virus meeting the above criteria AND with documented clinical inappropriateness or inability to tolerate Epclusa®:

- A. For naïve, non-cirrhotic patients, 12 weeks will be approved when used in combination with Sovaldi®.
- B. For naïve, cirrhotic patients, 24 weeks will be approved when used in combination with Sovaldi® and ribavirin. Ribavirin must be used.
- C. For non-cirrhotic patients who have failed to obtain a cure with a pegylated interferon/ribavirin regimen, 12 weeks will be approved when used in combination with Sovaldi®.
- D. For cirrhotic patients who are interferon ineligible and have failed to obtain a cure with a pegylated interferon/ribavirin regimen, 24 weeks will be approved when used in combination with Sovaldi® and weight-based ribavirin. Ribavirin must be used unless it was discontinued previously due to anemia (medical chart documentation required).
- E. For patients who are interferon ineligible and have failed to obtain a cure with a sofosbuvir/ribavirin regimen, 24 weeks will be approved when used in combination with Sovaldi® and weight-based ribavirin. Ribavirin must be used unless it was discontinued previously due to anemia (medical chart documentation required).

VieKira/VieKira XR Pak

Harvoni® and Zepatier® regimens are the preferred treatments for viral genotype 1. Therefore, documented clinical inappropriateness or inability to tolerate Harvoni® AND Zepatier® will be required prior to VieKira/VieKira XR Pak® approval.

Required Inclusion Criteria

Requests meeting all of criteria below will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients ≥ 18 years of age meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
 - A. Laboratory confirmed diagnosis of chronic hepatitis C genotype 1 virus; and,
 - B. 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., Epclusa®, Harvoni®, Sovaldi®, Zepatier®, Daklinza®, Olysio®, or Technivie®); 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.

VieKira/VirKira XR Pak (continued)

Approval Durations

VieKira/VieKira XR Pak® will be approved as follows in patients with genotype 1 virus meeting the above criteria AND with documented clinical inappropriateness or inability to tolerate Harvoni® AND Zepatier®:

- A. Non-cirrhotic, genotype 1b patients will be approved for 12 weeks total duration.
- B. Cirrhotic, genotype 1a patients who failed previous chronic hepatitis C treatment will be approved for 24 weeks total duration when used in combination with ribavirin.
- C. All others will be approved for 12 weeks total duration when used in combination with ribavirin.

Olysio

Harvoni® and Zepatier® regimens are the preferred treatments for viral genotype 1. Therefore, documented clinical inappropriateness or inability to tolerate Harvoni® AND Zepatier® will be required prior to Olysio® approval.

Required Inclusion Criteria

Requests meeting all of criteria below will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients ≥ 18 years of age meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
 - A. Laboratory confirmed diagnosis of chronic hepatitis C genotype 1 virus; and,
 - B. 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 may be in combination with Sovaldi® but not with any other direct acting antiviral (e.g., Eplclusa®, Harvoni®, Zepatier®, Daklinza®, Technivie®, 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.

Olysio (continued)

Approval Durations

Harvoni[®] or Zepatier[®] regimens are the preferred treatments for patients with genotypes 1 or 4 virus. Approval for treatment must include justification of why Harvoni[®] AND Zepatier[®] cannot be used. If approved, Olysio[®] regimens will be approved as follows:

1. Genotype 1 - Requests for Olysio[®] will be reviewed on a case by case basis. Harvoni[®] and Zepatier[®] regimens are the preferred treatments for patients with genotype 1 virus.
 - A. For patients without cirrhosis, Olysio[®] will be approved for a duration of 12 weeks, when used in combination with Sovaldi[®].
 - B. For patients with compensated cirrhosis, Olysio[®] will be approved for a duration of 24 weeks, when used in combination with Sovaldi[®] and for genotype 1a when no Q80K polymorphism is detected. Alternative regimens should be used for these patients.
2. Genotype 4 - Requests for Olysio[®] will be reviewed on a case by case basis. Harvoni[®] and Zepatier[®] regimens are the preferred treatments for patients with genotype 4 virus.
 - A. For patients without cirrhosis or with compensated cirrhosis with or without HIV-1 co-infection, Olysio[®] will be approved for a duration of 12 weeks, when used in combination with pegylated interferon and ribavirin. Pegylated interferon and ribavirin will continue for an additional duration of 12 or 36 weeks.

Technivie

Harvoni® and Zepatier® regimens are the preferred treatments for viral genotype 4. Therefore, documented clinical inappropriateness or inability to tolerate Harvoni® AND Zepatier® will be required prior to Technivie® approval.

Required Inclusion Criteria

Requests meeting all of criteria below will be approved.

1. Treatment is prescribed by a physician or advanced practice provider within a gastroenterology, hepatology, infectious disease or transplant specialty practice.
2. Patients ≥ 18 years of age meeting ALL the following disease criteria as evidenced by written documentation from the medical record:
 - A. Laboratory confirmed diagnosis of chronic hepatitis C genotype 4 virus; and,
 - B. Pretreatment viral load within one year of regimen start date; and,
 - C. No evidence of cirrhosis of the liver due to the fact that Technivie is not indicated for use in patients with cirrhosis of the liver.
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., Epclusa®, Harvoni®, Sovaldi®, Zepatier®, Daklinza®, Olysio®, 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 treatment completion.

Technivie (continued)

Approval Durations

Harvoni[®] or Zepatier[®] regimens are the preferred treatments for patients with genotype 4 virus. Approval for treatment must include justification of why Harvoni[®] AND Zepatier[®] cannot be used. If approved, Technivie[®] will be approved as follows:

1. Non-cirrhotic, genotype 4 patients will be approved when used in combination with ribavirin for 12 weeks total duration.