

Prior Authorization Criteria and Policy

Antiviral Agents for Hepatitis C Virus



Superior follows the Texas Vendor Drug Program clinical prior authorization criteria for Hepatitis C medications.

I. Eligibility

1. Patient is enrolled in Texas Medicaid and is greater than or equal to 18 years of age.
2. Patient has a diagnosis of chronic hepatitis C virus (HCV) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5, or 6. Genotype test results must be obtained within the previous 5 years from the date of prior authorization request.
3. Immediate treatment is assigned the highest priority for patients with advanced fibrosis (Metavir stage F3) or cirrhosis (Metavir stage F4), liver transplant recipients, and patients with hepatocellular carcinoma. Patients with Metavir scores less than stage 3 may not be approved.
4. Prescriber should be a Board Certified Gastroenterologist, Hepatologist, or Infectious Disease physician. A prescriber other than the above specialists may prescribe and assume responsibility and care for the patient when the prescriber is supervised by a specialist, or with consult from a specialist from the previous 90 days. A copy of written consult must be submitted. *Exceptions may be considered when a specialist is not available.*
5. Required laboratory values in Section 3 of the prior authorization form must be obtained within 90 days prior to the request for HCV treatment.
6. Q80K polymorphism testing is required for requests for treatment with Olysio within the previous 2 years.
7. NS5A resistance testing is required for requests for treatment with Daklinza or Zepatier in genotype 1a patients within the previous 2 years.
8. Child-Turcotte-Pugh Score must be assessed within 90 days prior to the request for HCV treatment.
9. Female patients' pregnancy status must be determined by a pregnancy test prior to the request for HCV treatment. The pregnancy test should be conducted as close to the start of treatment as possible, but no later than 90 days prior to the request. Pregnancy status must be confirmed negative for all ribavirin containing regimens. Pregnancy status is not required for age greater than 50, or for those documented as not able to become pregnant.
10. Patient must have one drug screening within 90 days prior to the request for HCV treatment.
11. Patient must be assessed for hepatitis B coinfection within 90 days prior to the request for HCV treatment.
12. Prescriber must provide required lab results at baseline, and treatment weeks 4 and 12.
13. Documentation of any additional supporting labs must be provided if requested by the patient's health care plan.

II. Treatment approval

1. Prior authorization is granted for 6 weeks per approval. A request using the *Antiviral Agents for Hepatitis C Virus Prior Authorization Form-Refill Request* should be submitted by 6 weeks, and every 6 weeks thereafter of therapy to facilitate continuation of therapy.
2. Prescriptions may be dispensed for a maximum 28 day supply.
3. Refill authorization is subject to approval based upon submission of labs at weeks 4 and 12. Request for refill prior authorization may be rejected if patient or prescriber are unable to provide the required labs.
4. Request for products other than a preferred product will require additional justification, including rationale for why a preferred product is not indicated for the patient. Request for a product other than a preferred product does not guarantee approval.

Preferred Hepatitis C Agents	
Direct Acting Antiviral	Other
Daklinza (daclatasvir) ⁵ Epclusa (sofosbuvir/velpatasvir)* <i>*Epclusa is preferred for genotypes 2 and 3 only</i> Technivie (ombitasvir/paritaprevir/ritonavir) Viekira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir) Viekira XR (ombitasvir/paritaprevir/ritonavir and dasabuvir)	PEG-Intron (peginterferon alfa-2b) ribavirin capsule/tablet
Non-Preferred Direct Acting Antivirals	
Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)	

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5. Daklinza is indicated for genotypes 1 and 3 in combination with Sovaldi (sofosbuvir), with or without ribavirin. Sovaldi is a non-preferred product and may not be approved in situations where a preferred product is appropriate. Therefore, use of Daklinza with Sovaldi will be limited to consideration for approval only in circumstances when another preferred product is not indicated.
6. Regimen approval is based on genotype, disease related conditions, concurrent drug therapies, and previous HCV treatment regimens.
7. Clients who transition to Medicaid from another health care plan while currently undergoing active HCV treatment will be allowed to continue the HCV treatment regimen without interruption regardless of drug status (preferred or non-preferred).
8. Prescriber and patient must review and sign the *Prescriber Certification* document.
9. Submission of incomplete or missing forms may result in denial of the request.

III. Additional Considerations

1. Patient's non-adherence to therapy for more than 14 days may result in discontinuation of prior authorization and additional refills may not be approved. Exceptions are considered in circumstances that are beyond patient or prescriber control. Documentation stating reason for gaps in therapy may be required at the request of the health plan.
2. Patients requiring retreatment will be assessed for approval on a case by case basis.
3. Lost or stolen medications may not be replaced.
4. For appeals and reconsiderations, dates of any test and/or laboratory results that fall outside of the required windows for submission will be considered valid if the date of the test and/or laboratory results were within the required window for submission at the time of the initial HCV prior authorization request. This policy is not applicable if more than 90 days have passed since the initial HCV prior authorization request.
5. HCV viral load is recommended at 12 weeks following completion of therapy. Prescribers should obtain and maintain records of viral load at 12 weeks after completion of therapy.