

**320-N - HEPATITIS C VIRUS (HCV) PRIOR AUTHORIZATION REQUIREMENTS  
FOR DIRECT ACTING ANTIVIRAL (DAA) MEDICATION TREATMENT**

EFFECTIVE DATES: 07/17/14, 01/01/18, 10/01/18, 10/01/21

APPROVAL DATES: 08/01/14, 03/15/15, 10/01/16, 07/06/17, 07/11/18, 07/15/21

**I. PURPOSE**

This Policy applies to ACC, ALTCS E/PD, DCS/Comprehensive Health Plan (CHP), DES/DDD (DDD), RBHA Contractors; Fee-For-Service (FFS) Programs including: the American Indian Health Program (AIHP), Tribal ALTCS, TRBHA, and all FFS populations, excluding Federal Emergency Services (FES). (For FES, refer to AMPM Chapter 1100). This Policy specifies prior authorization requirements for members for direct acting antiviral (DAA) medications for treatment of Hepatitis C Virus (HCV).

**II. DEFINITIONS**

Definitions are located on the AHCCCS website at: [AHCCCS Contract and Policy Dictionary](#).

**III. POLICY**

Prior authorization approval for coverage of Direct Acting Antiviral (DAA) medications for treatment of Hepatitis C Virus (HCV) is required for all members prior to initiating treatment. In order to obtain prior authorization approval, all of the following requirements shall be met:

1. Diagnosis of chronic HCV which has been confirmed by detectable serum HCV RNA by quantitative assay completed within the past 90 days from the date of the prior authorization request that includes the HCV genotype, viral resistance status (when applicable), hepatic status (Child Pugh Score) and HCV viral load.
2. Age of the member is Food and Drug Administration (FDA) approved for the specific HCV DAA product.
3. HCV DAA medications are prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.
4. The prescribing provider assesses the member's ability to adhere to the HCV DAA treatment plan and documents this assessment within the clinical record. For members that would benefit from adherence aids, the treating provider shall refer the member to a treatment adherence program.
5. Member agrees to adhere to the proposed course of treatment, including taking medications as prescribed, attending follow-up appointments, and, if applicable, participating in a treatment adherence program.

6. The member has been screened for Hepatitis A and B and shall have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity.

**A. TREATMENT MONITORING REQUIREMENTS**

1. The prescribing provider is required to monitor hemoglobin levels periodically when a member is prescribed ribavirin.
2. The prescribing provider is required to monitor HCV RNA levels obtained at 12 and 24 weeks post therapy completion to demonstrate the Sustained Virologic Response (SVR).

**B. HEPATITIS C RETREATMENT REQUIREMENTS**

For members who have HCV and a history of treatment with a DAA, the following criteria shall be met for DAA retreatment approval:

1. The member was adherent to previous DAA therapy as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record shall be provided which documents these adverse effects and recommendation of discontinuation by treatment provider.
2. The member's ability to adhere to the planned course of retreatment has been assessed by the treating provider and documented within the clinical record.
3. Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when:
  - a. Required for regimens whereby the FDA requires such testing prior to treatment to ensure clinical appropriateness, and
  - b. Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen.
4. HCV retreatment with a DAA shall not be approved when:
  - a. The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy,
  - b. A member was non-adherent to the initial DAA treatment regimen as evidenced by medical records and/or pharmacy prescription claims, or
  - c. Is considered an experimental service as specified in A.A.C. R9-22-203.

**C. LIMITATIONS**

DAA HCV treatment coverage is not provided for the following:

1. Monotherapy of Sofosbuvir (Sovaldi).
2. DAA dosages greater than the FDA approved maximum dosage.

3. Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request.
4. Members who do not agree to adhere to the proposed course of treatment, including participating in a treatment adherence program if applicable.
5. Members whose comorbidities are such that their life expectancy is one year or less.
6. Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.).
7. Greater than one DAA drug regimen used for retreatment.
8. Lost or stolen medication absent of good cause.
9. Fraudulent use of HCV DAA medications.

**D. REQUIRED DOCUMENTATION FOR SUBMISSION OF HCV PRIOR AUTHORIZATION REQUESTS**

In order for a prior authorization request for HCV DAA medications to be considered, the following minimum information shall be submitted by the prescribing provider for the member:

1. HCV treatment history and responses.
2. Evidence of Hepatitis A and Hepatitis B vaccinations or laboratory evidence of immunity.
3. Current medication list.
4. Laboratory results for all of the following:
  - a. HCV screen,
  - b. Genotype and current baseline viral load,
  - c. Total bilirubin,
  - d. Albumin,
  - e. International Normalized Ratio (INR),
  - f. Creatinine Clearance (CrCl) or Glomerular Filtration Rate (GFR),
  - g. Liver Function Tests (LFTs), and
  - h. Complete Blood Count (CBC).