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

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

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

I. PURPOSE

This Policy applies to AHCCCS Complete Care (ACC), ALTCS/EPD, DCS/CMDP (CMDP), DES/DDD (DDD), RBHA Contractors; and Fee-For-Services (FFS) Programs delineated within this Policy including: Tribal ALTCS, TRBHAs, and the American Indian Health Program (AIHP), and all FFS populations, excluding Federal Emergency Services (FES). (For FES, see AMPM Chapter 1100). This Policy delineates AHCCCS prior authorization requirements for Title XIX and XXI members 12 years and older for coverage of direct acting antiviral medications for treatment of Hepatitis C Virus (HCV). All such medications require prior authorization from AHCCCS for FFS members or Contractors, as applicable.

II. DEFINTIONS

None

III. POLICY

In order to obtain prior authorization approval of Hepatitis C direct acting antiviral medications, members shall meet all of the following requirements:

1. Diagnosis of chronic Hepatitis C infection status 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. Adult age $\geq$18 years or adolescent age between 12 and 18 years old,

3. Are prescribed HCV medications by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician,

4. Patient readiness has been assessed and patient attestation of compliance is submitted and on file in the member's medical record (prescribers shall use the Controlled Substances Prescription Monitoring Program [CSPMP] as a tool to aid in the review of compliance),

5. The member agrees to complete the regimen and understands the risks of reinfection and other contributors to liver disease and/or damage, through a signed attestation,

6. The prescribing clinician agrees to maintain HCV RNA levels obtained at 12 & 24-weeks post therapy completion to demonstrate the Sustained Virilogic Response (SVR),

7. 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, and

8. The member shall be in remission for the past three months from the request date for treatment, and shall be engaged in a substance use disorder treatment program at the time of the prior authorization and over the course of the treatment if the member has/had a substance use disorder in the past 12 months.

A. TREATMENT MONITORING REQUIREMENTS

1. Members prescribed HCV treatment shall participate in a treatment adherence program.

2. Providers are required to monitor hemoglobin levels periodically when a member is prescribed ribavirin.

B. HEPATITIS C RETREATMENT REQUIREMENTS

For members who have HCV and a history of treatment with a Direct Acting Antiviral (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. If a member has a substance use disorder in the past 12 months from the request date for treatment, the member shall be in remission for the past three months from the request date for treatment and shall be engaged in a substance use disorder treatment program at the time of the prior authorization request and over the course of treatment if the DAA medications are approved,

3. Member commits to the documented planned course of treatment including anticipated laboratory, imaging tests, and prescribing provider visits,

4. 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.

Hepatitis C Retreatment shall not be approved when:

1. The life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation, or by other directed therapy,

2. A member was non-adherent to the initial DAA treatment regimen as evidenced by medical records and/or pharmacy prescription claims, or

3. Is considered an experimental service as defined in A.A.C. R9-22-203. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA.

C. LIMITATIONS

Direct Acting Antiviral HCV treatment coverage is not provided for the following:

1. Monotherapy of:
   a. Daclatasvir (Daklinza),
   b. Simeprevir (Olysio),
   c. Sofosbuvir (Sovaldi),

2. Direct Acting Antiviral Dosages greater than the FDA approved maximum dosage,

3. Ombitasvir, Paritaprevir and Ritonavir (Technivie) or Ombitasvir, Paritaprevir and Ritonavir, Dasabuvir tablets (Viekira Pak) shall not be approved for members whose Child Pugh score is B or C,

4. Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request,

5. Members when there is documented non-adherence to prior HCV medications, HCV medical treatment, or failure to complete HCV disease evaluation appointments and laboratory and imaging procedures,

6. Members declining to participate in a treatment adherence program,

7. Members declining to participate in a substance abuse disorder treatment program,

8. Members whose comorbidities are such that their life expectancy is one year or less,

9. Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.), greater than one Direct Acting Antiviral drug regimen used for retreatment,

10. Lost or stolen medication absent of good cause, or

11. Fraudulent use of HCV medications.

D. REQUIRED DOCUMENTATION FOR SUBMISSION OF HCV PRIOR AUTHORIZATION REQUESTS

In order for a prior authorization request for HCV medications to be considered, the following minimum information shall be submitted 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, and

4. Laboratory results for all of the following:
   a. HCV screen,
   b. Genotype and current baseline viral load,
   c. Total bilirubin,
   d. Albumin,
   e. INR,
   f. CrCl or GFR,
   g. LFTs,
   h. CBC, and
   i. Drug/alcohol screen completed within the past 90 days.