

SHWT Proposed Hepatitis C Pharmaceutical Coverage Policy

Coverage for anti-viral medications prescribed for the treatment of Hepatitis C will be covered subject to all Medical Necessity and all other provisions of the Plan and will need to conform to applicable national evidenced based guidelines as selected by the Trust “Guidelines” (i.e. current American Association For The Study of Liver Diseases (AASLD) / (IDSA) Infectious Disease Society of America) subject to the following:

- I. Compliance with current Guidelines subject to formulary restrictions and additional applicable Plan provisions and policies with the exception of the following:
 - a. Individuals with longstanding infection without evidence of significant hepatic fibrosis. Significant fibrosis is defined as greater than Metavir stage 2 disease or the equivalent. The participant will be considered to have longstanding infection if they have no evidence of sero-conversion within the past 5 years or were born between the years 1945 and 1955. Evidence of sero-conversion will require previously obtained negative Hepatitis C serology followed by a test within the past 5 years documenting infection with the Hepatitis C virus.
 - b. Participants with Active Substance Abuse. Active Substance Abuse is defined as the use of non-prescribed injectable or other non-prescribed drugs or substances within the past 12 months. Participants with Active Substance Abuse will be eligible for treatment providing that they agree to participate in the Trust’s behavioral health case management program and comply with all plan requirements including physician treatment recommendations with regard to treatment of their substance abuse issues and can demonstrate that they have abstained from the use of any non-prescribed injectable or other non-prescribed substances for a period of not less than 6 months while undergoing program assessment and treatment.
 - c. Participants with Active Alcohol Abuse. Active Alcohol Abuse is defined to be the ongoing misuse of alcohol where there is a known medical or psychiatric contraindication to ongoing use within the past 12 months. Participants with Active Alcohol Abuse will be eligible for treatment providing that they agree to participate in the Trust’s behavioral case management program and comply with all plan requirements including physician treatment recommendations with regard to treatment of their Active

Alcohol Abuse issues and can demonstrate that they have abstained from the use of alcohol or other non-prescribed substances for a period of not less than 6 months while undergoing assessment and treatment.

- d. Participants with evidence of known terminal disease, with life expectancy \leq 12 months.
 - e. Participants with treatment being ordered by a licensed practitioner who is not a Board Certified Gastroenterologist, Hepatologist, or Infectious Disease Practitioner or other Board Certified Physician “Credentialed Specialist” experienced in the treatment of patients with Hepatitis C unless the participant has been evaluated by a Credentialed Specialist within the prior 6 months and the requested treatment has been recommended by the Credentialed Specialist.
- II. Participants without a history of longstanding Hepatitis C infection (born after 1955 or with a history of recent sero-conversion as defined above) will qualify for treatment with Hepatitis C anti-viral medications regardless of stage of fibrosis subject to the following requirements:
- a. The participant must present a negative standard urine drug screen obtained within 30 days prior to initiation of therapy if requested by the Trust or its Pharmacy Benefit Manager.
 - b. The treatment regimen prescribed is not for an indication outside of the FDA approved labeling and is prescribed as part of an FDA approved treatment regimen.
 - c. In the opinion of the prescriber, the patient is able to make appropriate decisions about treatment, comply with dosing and other instructions, and is capable of complying with appropriate physician treatment recommendations and of completing therapy. Patient non-compliance including failure to obtain required follow-up visits and required testing (i.e. HCV RNA levels during the first 8 weeks of therapy, continued alcohol or prohibited illicit substance use) may result in termination of approval for additional therapy.