Clinical Policy: Hepatitis C Agents

Reference Number: PHW.PDL.064
Effective Date: 01/01/2020
Last Review Date: 11/2025

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Hepatitis C Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Hepatitis C Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hepatitis C Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hepatitis C Agent.

2. A Hepatitis C Agent with a prescribed quantity that exceeds the quantity limit.

3. A direct-acting antiviral (DAA) Hepatitis C Agent when there is a record of a recent claim for another DAA Hepatitis C Agent in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For a non-preferred DAA Hepatitis C Agent, **all** of the following:

   a. If genotyping is recommended by the American Association for the Study of Liver Diseases (AASLD), has documentation of genotype**,**

   b. Is prescribed a drug regimen that is consistent with U.S. Food and Drug Administration (FDA)-approved labeling, nationally recognized compendia, or peer-reviewed medical literature,

   c. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

d. Has a cirrhosis assessment documented by a recent noninvasive test (e.g., blood test or imaging, a Fibroscan, FIB-4 calculation, or findings on physical examination),

e. If the member has received prior treatment(s) for hepatitis C, documentation of previous hepatitis C treatment regimens,

f. If resistance-associated substitution (RAS) testing is recommended by the AASLD, has documentation of recommended RAS testing and is prescribed an AASLD-recommended drug regimen based on the documented results of a NS5A RAS screening,

g. **One** of the following:

i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatitis C Agents appropriate for the member's genotype according to peer-reviewed medical literature
ii. Is currently receiving treatment with the same non-preferred Hepatitis C Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

2. For all other non-preferred Hepatitis C Agents, all of the following:

a. Is being treated for a diagnosis that is indicated in the FDA-approved package labeling OR a medically accepted indication,
b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
c. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
d. Has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines;

3. For therapeutic duplication, has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines; AND

4. If the prescription for a Hepatitis C Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hepatitis C Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of Hepatitis C Agents will be for the full recommended duration of treatment based on package labeling or consensus treatment guidelines.

Mavyret (glecaprevir/pibrentasvir)	Up to a total of 16 weeks
Ribasphere, Moderiba, Rebetol (ribavirin)	Coincides with Duration for Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Zepatier or Viekira Pak Authorization
Epclusa (sofosbuvir/velpatasvir)	Up to a total of 24 weeks
Zepatier (elbasvir/grazoprevir)	Up to a total of 16 weeks
Daklinza (daclatasvir)	Up to a total of 24 weeks
Harvoni (ledipasvir/sofosbuvir)	Up to a total of 24 weeks
Pegasys (peginterferon alfa-2a) **Pegintron (peginterferon alfa-2b)**	Interferon-based treatment regimens are no longer recommended by the 2017 American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA) HCV guidance due to the advent of safe and effective direct acting antivirals. Please refer to peer-reviewed medical literature for approval duration, if needed.
Sovaldi (sofosbuvir)	Adults: up to a total of 24 weeks Pediatrics: 12 weeks for genotype 2; 24 weeks for genotype 3

Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir)	Up to a total of 12 weeks
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Up to a total of 12 weeks

E. References

1. AASLD/IDSA/IAS-USA. Recommendations for Testing, Managing, and Treating Hepatitis C. www.hcvguidelines.org. Accessed June 24, 2022.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021.	11/2020
Q1 2022: policy revised according to DHS revisions effective 01/03/2022.	10/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023.	10/2022
Q3 2023: policy revised according to DHS revisions effective 07/10/2023.	07/2023
Q1 2024: policy revised according to DHS revisions effective 01/08/2024.	11/2023
Q1 2025 annual review: no changes.	11/2024
Q1 2026: policy revised according to DHS revisions effective 01/05/2026.	11/2025