

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
HEPATITIS C AGENTS

Proposed Effective Date: January 5, 2026

Proposed revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

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. See the Preferred Drug List (PDL) for the list of preferred Hepatitis C Agents at: <https://papdl.com/preferred-drug-list>.
2. A Hepatitis C Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits>.
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. Revisions to 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 beneficiary:

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 beneficiary has received prior treatment(s) for hepatitis C, has documentation of

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
HEPATITIS C AGENTS

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 beneficiary'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);

AND

- 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 U.S. Food and Drug Administration (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;**

AND

- 3. For therapeutic duplication, has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines; **AND**
- 4. If a 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 the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to

PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
HEPATITIS C AGENTS

meet the medical needs of the beneficiary, 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 beneficiary.

D. Dose and Duration of Therapy

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

E. References

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