


<b>ISSUE DATE</b>  November 9, 2022	<b>EFFECTIVE DATE</b>  January 9, 2023	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Hepatitis C Agents – Pharmacy Services	<b>BY</b>   Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs	

**IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMiSe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMiSe-Enrollment.aspx>.

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Hepatitis C Agents submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Hepatitis C Agents will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Hepatitis C Agents to the appropriate managed care organization.

**BACKGROUND:**

*01-22-62	09-22-61	27-22-49	33-22-59
02-22-46	11-22-46	30-22-52	
03-22-45	14-22-46	31-22-65	
08-22-70	24-22-54	32-22-46	

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included in the Preferred Drug List (PDL).
- Changes in the status of drugs and products on the PDL from preferred to non-preferred and non-preferred to preferred.
- New quantity limits.
- Therapeutic classes of drugs and products to be added to or deleted from the PDL.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

**DISCUSSION:**

During the September 13, 2022, meeting, the P&T Committee recommended revising the guidelines to determine medical necessity of Hepatitis C Agents to clarify the guideline related to liver fibrosis to reflect the recommendations included in the American Association for the Study of Liver Diseases/Infectious Disease Society of America HCV Guidance.

The revisions to the guidelines to determine medical necessity of prescriptions for Hepatitis C Agents submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Hepatitis C Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Hepatitis C Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs and products that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

**RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I  
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II  
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**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.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
3. A hepatitis C virus (HCV) direct-acting antiviral (DAA).

**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 beneficiary:

1. Has documentation of detectable quantitative HCV RNA at baseline; **AND**
2. If genotyping is recommended by the American Association for the Study of Liver Diseases (AASLD), has documentation of genotype; **AND**
3. Is prescribed a drug regimen that is consistent with FDA-approved labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Has a cirrhosis assessment documented by a recent noninvasive test (e.g., blood test or imaging, a Fibroscan, or findings on physical examination); **AND**
6. If beneficiary has received prior treatment(s) for hepatitis C, documentation of previous hepatitis C treatment regimens; **AND**
7. Has documented results of HIV screening (HIV Ag/Ab); **AND**
8. 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; **AND**

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9. For a non-preferred Hepatitis C Agent, **one** of the following:
- a. 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
  - b. 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**

10. 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 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 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](http://www.hcvguidelines.org). Accessed June 24, 2022.