

ISSUE DATE November 9, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below
SUBJECT Prior Authorization of Hepatitis C Agents – Pharmacy Services	BY  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 delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Hepatitis C Agents to the appropriate managed care organization.

*01-20-24	09-20-23	27-20-19	33-20-20
02-20-17	11-20-17	30-20-16	
03-20-17	14-20-18	31-20-24	
08-20-27	24-20-18	32-20-16	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type.</p> <p>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.</p>

BACKGROUND:

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

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

DISCUSSION:

During the August 11, 2020, meeting, the P&T Committee recommended revisions to the guidelines to determine medical necessity of Hepatitis C Agents regarding testing for hepatitis C virus RNA, genotype, and resistance-associated substitutions to be consistent with updated consensus treatment guidelines from the American Association for the Study of Liver Diseases.

The revisions to the guidelines to determine medical necessity of Hepatitis C Agents, 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 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 prescription for Interferon.
4. 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 Metavir fibrosis score documented by a recent noninvasive test (e.g., blood test or imaging, a Fibroscan, or findings on physical examination); **AND**
6. Has documentation of **one** of the following:
 - a. A complete hepatitis B immunization series
 - b. Hepatitis B screening (sAb, sAg, and cAb) and **all** of the following:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- i. If positive for hepatitis B sAg, quantitative HBV DNA results,
- ii. If there is detectable HBV DNA, a treatment plan for hepatitis B consistent with AASLD recommendations,
- iii. If negative for hepatitis B sAb, a hepatitis B immunization plan or counseling to receive the hepatitis B immunization series;

AND

7. Has a documented HIV screening (HIV Ag/Ab) and, if confirmed positive by HIV-1/HIV-2 differentiation immunoassay, **one** of the following:
 - a. Is being treated for HIV
 - b. If not being treated for HIV, the medical record documents the rationale for the beneficiary not being treated;

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**
9. Does not have a life expectancy of less than 12 months due to non-liver-related comorbid conditions; **AND**
10. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**
11. For a non-preferred Hepatitis C Agent, **one** of the following:
 - a. Has a history of therapeutic failure, contraindication, or 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;

AND

12. Has a documented commitment to adherence with the planned course of treatment and mutual prescriber and Departmental monitoring; **AND**
13. 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 consistent with package labeling or peer-reviewed medical literature.

E. References

1. Olysio [prescribing information]. Titusville, NJ: Janssen Therapeutics; Revised November 2017.
2. Sovaldi [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; Revised November 2017.
3. Use in Patients with HCV and HIV Coinfection—OLYSIO. Janssen MD, Professional Information Recourse. Janssen Scientific Affairs, modified on November 27, 2013.
4. Harvoni [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; Revised November 2017.
5. Viekira Pak [prescribing information]. North Chicago, IL: AbbVie, Inc.; Revised July 2018.
6. AASLD/IDSA/IAS-USA. Recommendations for Testing, Managing, and Treating Hepatitis C. www.hcvguidelines.org. Accessed January 31, 2020.
7. US Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health. Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations. <https://www.hepatitis.va.gov/pdf/treatment-considerations-2017-10-18.pdf> Accessed August 15, 2018.
8. Myers RP, Shah H, Burak KW et al. An update on the management of chronic hepatitis C: 2015 consensus guidelines from the Canadian Association for the Study of the Liver. *Can J Gastroenterol Hepatol* 2015; Special Article 0(0):19-34.
9. European Association for the Study of the Liver. EASL Recommendations on Treatment of Hepatitis C 2015. www.easl.eu/medias/cpg/HEPC-2015/Full-report.pdf. Accessed May 4, 2015.
10. US Department of Veterans Affairs National Hepatitis C Resource Center Program and the HIV, Hepatitis, and Public Health Pathogens Programs in the Office of Patient Care Services Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations. Updated September 22, 2016.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

11. European Association for the Study of the Liver. EASL Recommendations on Treatment of Hepatitis C 2016.
12. MedWatch The FDA Safety Information and Adverse Event Reporting Program, Safety Alerts for Human Medical Products: Direct-Acting Antivirals for Hepatitis C: Drug Safety Communication - Risk of Hepatitis B Reactivating. Posted October 4, 2016.
13. Centers for Disease Control and Prevention. Testing and Public Health Management of Persons with Chronic Hepatitis B Virus Infection – Interpretation of Hepatitis B Serologic Test Results. <https://www.cdc.gov/hepatitis/hbv/pdfs/SerologicChartv8.pdf>. Accessed August 15, 2018.