

| | | |
|---|---|---------------------------------|
| ISSUE DATE December 12, 2018 | EFFECTIVE DATE December 17, 2018 | 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:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 and providing services in the fee-for-service delivery system, including pharmacy services to residents of long-term care facilities. Providers rendering services under the MA managed care delivery system should address any questions related to Hepatitis C Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the DHS

| | | | |
|-----------|----------|----------|----------|
| *01-18-28 | 09-18-29 | 27-18-28 | 33-18-28 |
| 02-18-23 | 11-18-23 | 30-18-23 | |
| 03-18-24 | 14-18-24 | 31-18-29 | |
| 08-18-31 | 24-18-25 | 32-18-23 | |

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 Web site at
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

The U.S. Food and Drug Administration (FDA) published a warning in October of 2016 regarding the risk of hepatitis B virus (HBV) reactivation in any patient who has a current or previous infection with HBV and is treated with direct-acting antivirals (DAAs) for hepatitis C. In response to this warning DHS published revised clinical review guidelines to determine the medical necessity of Hepatitis C Agents submitted for prior authorization.

During the September 25, 2018, DUR Board meeting, the DUR Board recommended that DHS update the medical necessity guidelines for Hepatitis C Agents to further clarify when HBV DNA results should be obtained and the expectation regarding HBV vaccination. The revised guidelines to determine the medical necessity of Hepatitis C Agents recommended by the DUR Board were subject to public review and comment, and subsequently approved for implementation by DHS.

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. DHS 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

SECTION II
Hepatitis C Agents

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. Interferon.
2. Hepatitis C Virus (HCV) Direct-Acting Antivirals (DAAs).
3. 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>.
4. 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: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

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 a diagnosis of chronic hepatitis C with documented genotyping
AND
2. Is prescribed a dose and length of therapy that is consistent with FDA-approved labeling or peer-reviewed medical literature
AND
3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature
AND
4. If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of a referral for substance use disorder treatment

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

5. Has a Metavir fibrosis score documented by a recent noninvasive test such as a blood test or imaging, a Fibroscan, or findings on physical examination

AND

6. Has documentation of:
 - a. A complete hepatitis B immunization series

OR

- b. Hepatitis B screening (sAb, sAg, and cAb)

AND

- c. If positive for hepatitis B sAg, quantitative HBV DNA results

AND

- d. If there is detectable HBV DNA, a treatment plan for hepatitis B consistent with AASLD recommendations

AND

- e. 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:
 - a. Is being treated for HIV

OR

- b. If not being treated for HIV, the medical record documents the rationale for the beneficiary not being treated

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

8. Has documentation of AASLD-recommended resistance-associated substitution (RAS) testing and is prescribed a drug regimen in accordance with AASLD guidance

AND

9. If genotype 1a or had a previous treatment failure with a direct-acting antiretroviral (DAA) regimen is prescribed an AASLD recommended drug regimen based on the documented results of a NS5A RAS screening

AND

10. Does not have a life expectancy of less than 12 months due to non-liver-related comorbid conditions

AND

11. Has a documented quantitative HCV RNA at baseline that was tested within the past 3 months

AND

12. Corrected or addressed the causes of non-adherence to a previously prescribed hepatitis C treatment regimen if the beneficiary has a history of failed treatment due to non-adherence

AND

13. 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

14. When prescribed ribavirin:
- a. Has a pretreatment hemoglobin of at least 10 g/dL

AND

- b. If female:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- i. Had a negative pregnancy test immediately prior to initiating therapy

AND

- ii. Will be using two or more forms of contraception

AND

- iii. Will have monthly pregnancy tests during therapy

AND

- 15. For non-preferred Hepatitis C Agents:

- a. Has a documented 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

OR

- b. Is currently receiving treatment with the same non-preferred Hepatitis C Agent

AND

- 16. Has a documented commitment to adherence with the planned course of treatment and mutual prescriber and Departmental monitoring

AND

- 17. 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 the Quantity Limits Chapter.

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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.

All requests for prior authorization of a prescription for a Hepatitis C Agent for re-treatment with a Hepatitis C Agent will be automatically forwarded to a physician reviewer for a medical necessity determination.

The physician reviewer will prior authorize the prescription when:

1. The guidelines in Section B. are met for re-treatment **OR**
2. 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 August 15, 2018.
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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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.
 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.