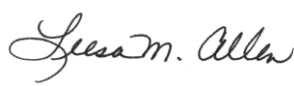


<b>ISSUE DATE</b> June 30, 2015	<b>EFFECTIVE DATE</b> July 20, 2015	<b>NUMBER</b> *See below
<b>SUBJECT</b>  Prior Authorization of Hepatitis C Agents – Pharmacy Service		<b>BY</b>   Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

## **PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Hepatitis C Agents, including the type of medical information needed to evaluate requests for medical necessity.

## **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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

## **BACKGROUND:**

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to 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, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

*01-15-21	09-15-21	27-15-18	
02-15-18	11-15-18	30-15-18	
03-15-18	14-15-18	31-15-21	
08-15-21	24-15-19	32-15-18	33-15-20

**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.state.pa.us/provider/healthcaremedicalassistance/index.htm>

**DISCUSSION:**

During the May 20, 2015, meeting, the P&T Committee recommended edits to the guidelines to determine medical necessity of Hepatitis C Agents to reflect updated national and international guidelines that were recently revised to include newly available treatment options. The updated guidelines to determine medical necessity were subject to public review and comment, and subsequently approved for implementation by the Department. The revised clinical review guidelines to determine the medical necessity of Hepatitis C Agents are included in the attached updated provider handbook pages.

**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 chapters 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
3. Non-preferred Hepatitis C Agents - See the most recent version of the Preferred Drug List (PDL), which includes a list of preferred Hepatitis C Agents, at:  
[www.providersynergies.com/services/documents/PAM\\_PDL.pdf](http://www.providersynergies.com/services/documents/PAM_PDL.pdf)
4. A prescription for a Hepatitis C Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:  
<http://www.dhs.state.pa.us/provider/doingbusinesswithdhs/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 recipient:

1. Has a diagnosis of chronic Hepatitis C with documented genotyping

**AND**

2. Is prescribed the medication by a specialist (infectious disease, gastroenterology, hepatology, or transplant)

**AND**

3. Is prescribed a dose and length of therapy that is consistent with FDA approved labeling or peer-reviewed medical literature

**AND**

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4. Is 18 years of age or older

**AND**

5. 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

**AND**

6. Has one of the following:

- a. A Metavir fibrosis score of F2-F4 documented by a recent:

- i. Non-invasive test such as a blood test or imaging with evidence of liver fibrosis, a Fibroscan, or findings on physical exam consistent with substantial or advanced fibrosis or cirrhosis

**OR**

- ii. An invasive test such as a liver biopsy

**OR**

- b. Severe extra-hepatic manifestations of Hepatitis C

**OR**

- c. HIV or HBV co-infection

**OR**

- d. History of a liver transplant

**AND**

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

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**AND**

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

**AND**

9. Corrected or addressed the causes of non-adherence if the recipient has a history of failed treatment due to non-adherence

**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 recipient of the risks associated with the use of both medications when they interact)

**AND**

11. When prescribed ribavirin:

- a. Has a pretreatment hemoglobin of at least 10 g/dL

**AND**

- b. If female:

- 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**

12. For non-preferred Hepatitis C Agents:

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- a. Has a documented history of therapeutic failure, contraindication or intolerance to the preferred Hepatitis C Agents appropriate for the recipient's genotype according to peer-reviewed medical literature.

**OR**

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

**AND**

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

**OR**

- 14. 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 recipient.

In addition, if a prescription for either a preferred or non-preferred Hepatitis C Agent is in 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 request for prior authorization 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 recipient.

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.

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The physician reviewer will prior authorize the prescription when:

1. The guidelines for re-treatment in Section B. are met, **OR**
2. In the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

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. Resources

1. Olysio [prescribing information]. Titusville, NJ: Janssen Therapeutics; Revised April 2015.
2. Sovaldi [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; Revised March 2015.
3. Use in Patients with HCV and HIV Coinfection—OLYSIO. JanssenMD, Professional Information Recourse. Janssen Scientific Affairs, modified on November 27, 2013.
4. Harvoni [prescribing information]. Foster City, CA: Gilead Sciences, Inc.; Revised March 2015.
5. Viekira Pak [prescribing information]. North Chicago, IL: AbbVie, Inc.; Revised March 2015.
6. AASLD/IDSA/IAS-USA. Recommendations for Testing, Managing, and Treating Hepatitis C. [www.hcvguidelines.org](http://www.hcvguidelines.org). Accessed May 4, 2015.
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. [www.hepatitis.va.gov/pdf/treatment-considerations-2015-02.pdf](http://www.hepatitis.va.gov/pdf/treatment-considerations-2015-02.pdf). Accessed May 4, 2015
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](http://www.easl.eu/medias/cpg/HEPC-2015/Full-report.pdf). Accessed May 4, 2015.