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/promis/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is issue updated handbook pages for Hepatitis C Agents 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 (FFS) and managed care delivery systems, including pharmacy services to residents of long term care facilities.

BACKGROUND:

| *01-17-30 | 09-17-28 | 27-17-27 |
| 02-17-26 | 11-17-26 | 30-17-27 |
| 03-17-26 | 14-17-26 | 31-17-30 |
| 08-17-32 | 24-17-27 | 32-17-26 |
| 33-17-29 |

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
The Department of Human Services’ (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and 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 the medical necessity of prescriptions submitted for prior authorization.

**DISCUSSION:**

During the May 17, 2016 P&T Committee meeting, the Committee recommended that Metavir fibrosis scores be removed from the guidelines to determine the medical necessity of Hepatitis C Agents. The Department carefully deliberated the recommendation and concluded that the recommendation is consistent with the Food and Drug Administration (FDA) approved package insert and current medically accepted treatment guidelines.

The Department will phase in implementation of the P&T Committee’s recommendation. Effective July 1, 2017, the clinical review guidelines to determine medical necessity will be revised to incorporate a Metavir fibrosis score of F1 to F4. The current guidelines that recognize severe extra-hepatic manifestations of Hepatitis C, HIV or HBV co-infection, and a history of a liver transplant when determining medical necessity will remain in effect. Effective January 1, 2018, the clinical review guidelines to determine medical necessity will be revised to incorporate a Metavir fibrosis score of F0 to F4.

The recommended revision to the guidelines to determine the medical necessity of Hepatitis C Agents to reflect a Metavir fibrosis score of F1-F4, effective July 1, 2017, were submitted to the Medical Assistance Advisory Committee for review and comment.

**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

SECTION II
Hepatitis C Agents
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 - The most recent version of the Preferred Drug List (PDL), which includes a list of preferred Hepatitis C Agents, is available at: https://papdl.com/preferred-drug-list

4. 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/pharmacieservices/quantitylimetlist/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

1 July 1, 2017
(Replacing July 20, 2015)
AND

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 F1-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 examination 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

2

July 1, 2017
(Replacing July 20, 2015)
7. Does not have a life expectancy of less than 12 months due to non-liver-related comorbid conditions

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 to a previously prescribed Hepatitis C treatment regimen 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

3 July 1, 2017
(Replacing July 20, 2015)
12. 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 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 prescriber and Departmental monitoring

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 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.

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 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.