Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/2020**
Policy Number: PHW.PDL.064	**Effective Date: 01/05/2021** **Revision Date: 11/2020**
Policy Name: Hepatitis C Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021: policy revised according to DHS revisions effective 01/05/2021.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Hepatitis C Agents

Reference Number: PHW.PDL.064
Effective Date: 01/01/2020
Last Review Date: 11/2020

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Hepatitis C Agents are **medically necessary** when the following criteria are met:

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.
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 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:

        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 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 PA.CP.PMN.59 Quantity Limit Override.

    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 consistent with package labeling, AASLD/IDSA, or peer-reviewed medical literature.

Mavyret (glecaprevir/pibrentasvir)	Up to a total of 16 weeks
Ribasphere, Moderiba, Rebetol (ribavirin)	Coincides with Duration for Daklinza, Epclusa, Harvoni, Olysio, Sovaldi, Technivie, Zepatier or Viekira Pak Authorization
Epclusa (sofosbuvir/velpatasvir)	Up to a total of 24 weeks
Zepatier (elbasvir/grazoprevir)	Up to a total of 16 weeks
Daklinza (daclatasvir)	Up to a total of 24 weeks
Harvoni (ledipasvir/sofosbuvir)	Up to a total of 24 weeks
Pegasys (peginterferon alfa-2a) **Pegintron (peginterferon alfa-2b)**	Interferon-based treatment regimens are no longer recommended by the 2017 American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA) HCV guidance

	due to the advent of safe and effective direct acting antivirals. Please refer to peer-reviewed medical literature for approval duration, if needed.
Sovaldi (sofosbuvir)	Adults: up to a total of 24 weeks Pediatrics: 12 weeks for genotype 2; 24 weeks for genotype 3
Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir)	Up to a total of 12 weeks
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Up to a total of 12 weeks

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.
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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021.	11/2020