JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS092
		Effective Date	04/15/2015
		Review Date	10/19/2022
	Subject **PPMCO Hepatitis C (HCV) Therapy: Harvoni, Zepatier, Epclusa, Mavyret, Vosevi**	*Revision Date*	07/28/2022
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Epclusa, Harvoni, Hepatitis C, Mavyret, Vosevi, Zepatier

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I. POLICY

A. Harvoni®, Zepatier®, Epclusa®, Mavyret®, and Vosevi® will require prior authorization for outpatient prescription drug benefit coverage to ensure the medications are used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy Pharm 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Policy Criteria may differ for each medication (listed below) based on member genotype and sub-genotype. All coverage request are subject to current Maryland Department of Health (MDH) clinical criteria.

B. Please note that this policy is a guidance for determining medication coverage. The Maryland Department of Health may review any individual request for coverage eligibility. In such cases, its decision will supersede the contents of this policy.

III. PROCESS FOR INITIATION OF REQUEST

A. Hepatitis C medication prior authorization requests for Mavyret, Harvoni, Epclusa, Zepatier, and Vosevi are required to be submitted on the drug-specific prior authorization forms found at: https://www.hopkinsmedicine.org/johns_hopkins_healthcare/providers_physicians/our_plans/priority_partners/pp_pharmacy_drug_forms.

B. Incorrect, incomplete, or outdated versions of authorization request forms, as well as those not including supporting documentation may be returned to the requesting provider for completion. This may delay the start of the prior authorization process.

IV. DIAGNOSIS/PRE–TREATMENT EVALUATION

The medication request must meet the following requirements:

A. The patient must have chronic hepatitis C, with genotype and sub-genotype specified*, to determine the length of therapy.
   1. Chronic hepatitis C is defined as infection that has been present for 6 months or greater, as evidenced by one of the following:
      a. Two lab tests (HCV antibody, HCV RNA, or HCV genotype) completed 6 months apart
      b. HCV diagnosis was reported 6 months ago or longer, and documented in the prescribers' clinical notes from past office visit(s)
      c. Risk of HCV exposure from greater than 6 months ago has been documented in the prescribers' notes from past office visit(s)
   2. *Please note: Documentation of genotype is not required in the treatment of HCV-Uninfected recipients of non-liver organs from HCV-Viremic Donors

B. If the patient has had prior exposure to DAA therapy, a pre-DAA genotype and post-DAA genotype must be documented.

C. Liver biopsy or another accepted test (ex. fibrosure, hepascore/fibroscore, fibroscan, point shear wave elastography (PSWE), acoustic radiation force impulse imaging (AFRI) has demonstrated a liver fibrosis status.

D. Documentation of the patient's HIV status, and if the patient is HIV positive, the current antiretroviral regimen and degree of viral suppression within 180 days of request.

E. Documentation of the patient's HBV status, and if the patient has active HBV disease, the current antiretroviral regimen and degree of viral suppression within 180 days of request.

F. Clinical documentation supporting diagnosis, prior hepatitis C treatment history, and planned treatment, must be dated within 180 days of prior authorization request unless the patient is cirrhotic; if the patient has cirrhosis, clinical documentation must be dated within 90 days of prior authorization request

G. Baseline laboratory values, including HCV RNA viral load, must be dated within 180 days of prior authorization requests unless the patient is cirrhotic; if the patient has cirrhosis, laboratory values must be dated within 90 days of prior authorization request.

H. Providers must assess and document the patient’s ability to adhere to therapy.

I. Providers must document drug resistance testing as indicated.

V. PATIENT TREATMENT PLAN

A. The patient must have a treatment plan developed by, or in collaboration with, a physician with expertise in Hepatitis C management. Sample treatment plan documents are available for use.

B. If the patient or their partner is of childbearing age, and has been prescribed a ribavirin-containing regimen, she must utilize 2 forms of contraception for the duration of therapy, as well as for 6 months post-treatment.

VI. DRUG THERAPY SELECTIONS

A. **Glecaprevir-Pibrentasvir (Mavyret®)** may be approved when the following has been met:
   1. Patient is 3 years of age or older, and treatment naïve to glecaprevir and pibrentasvir
   2. The pre-treatment evaluation criteria above have been met
   3. The requested dosing is one of the following:
      a. Adult patients, pediatric patients 12 years of age or older or weighing more than 45kg: 84 tablets/28 days (three tablets once daily dosing)
      b. Pediatric patients weighing less than 45kg: Weight-based dosing using 50 mg/20 mg oral pellet packets once daily (can range from three to five oral pellet packets once daily)
   4. The length of authorization is 8 weeks, 12 weeks, or 16 weeks, based on treatment experience and cirrhosis (Please see Appendix A for therapy regimen details)

B. **Ledipasvir-sofosbuvir (Harvoni®)** may be approved when the following has been met:
   1. Patient is 3 years of age or older, and treatment naïve to ledipasvir and sofosbuvir
   2. The pre-treatment evaluation criteria above have been met
   3. Patient has a contraindication to the preferred agent (Mavyret), or a medical condition/diagnosis that precludes the use of the preferred agent (Mavyret)
   4. Patient will not be using ledipasvir/sofosbuvir and P-gp inducers (e.g. rifampin, St. John's Wort) concomitantly. The use of these products together is not recommended due to the potential for significant decreases in ledipasvir and sofofbuvir plasma concentrations, which may reduce its therapeutic effect.
   5. The requested dosing is one of the following:
      a. Adult patients: 28 tablets or pellets/28 days (once daily dosing)
      b. Pediatric patients: Weight-based dosing using 90 mg/400 mg tablets, 45 mg/200 mg tablets, 45 mg/200 mg oral pellet packets, or 33.75 mg/150 mg oral pellet packets once daily (daily dose can range from 33.75 mg/150 mg per day to 90 mg/400 mg per day)
   6. The length of authorization is 8 weeks, 12 weeks, or 24 weeks, based on treatment experience and cirrhosis (Please see Appendix A for therapy regimen details)

C. **Elbasvir-Grazoprevir (Zepatier®)** may be approved when the following has been met:
   1. Patient is 12 years of age or older, and treatment naïve to elbasvir and grazoprevir
   2. The pre-treatment evaluation criteria above have been met
   3. Patient has a contraindication to preferred agent (Mavyret) or a medical condition/diagnosis that precludes the use of preferred agent (Mavyret)
   4. Patient has undergone genotype testing for baseline NS5A polymorphisms in order to determine treatment length
   5. The requested quantity is 28 tablets/28 days (once daily dosing)
   6. The length of authorization is 12 weeks or 16 weeks, based on treatment experience and cirrhosis (Please see Appendix A for therapy regimen details)

D. **Sofosbuvir-Velpatasvir (Epclusa®)** may be approved when the following has been met:
   1. Patient is 3 years of age or older, and treatment naïve to velpatasvir and sofosbuvir
   2. The pre-treatment evaluation criteria above have been met
   3. Patient has a contraindication to preferred agent (Mavyret) or a medical condition/diagnosis that precludes the use of preferred agent (Mavyret)
   4. The requested dosing is one of the following:
      a. Adult patients: 28 tablets/28 days (once daily dosing)

b. Pediatric patients: Weight-based dosing using 400 mg/100 mg tablets, 200 mg/50 mg tablets, 200 mg/50mg oral pellet packets, or 150 mg/ 37.5 mg oral pellet packets (daily dose can range from 150 mg/37.5 mg per day to 400 mg/100 mg per day)

5. The length of authorization is 12 weeks (Please see Appendix A for therapy regimen details)

E. **Sofosbuvir-Velpatasvir-Voxilaprevir (Vosevi®)** may be approved when the following has been met:
1. Patient is 18 years of age or older
2. The pre-treatment evaluation criteria above have been met
3. Patient has had trial and failure of a previous hepatitis C treatment regimen containing an NS5A inhibitor (e.g. Mavyret, Harvoni, Zepatier, Epclusa), or sofosbuvir without an NS5A inhibitor
4. The requested quantity is 28 tablets/28 days (once daily dosing)
5. The length of authorization is 12 weeks (Please see Appendix A for therapy regimen details)

VII. EXCLUSIONS

A. Mavyret, Harvoni, Zepatier, Epclusa, and Vosevi will not be approved for uses that are not FDA-approved, or MDH policy-supported.

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

VIII. HCV TREATMENT DEFINITIONS

- **Chronic Infection**: HCV infection that has been present for 6 months, or greater.
- **Retreatment**: Previous exposure to an HCV treatment direct acting antiviral (DAA) regimen, which does NOT result in achievement of SVR, and there is current need for an additional course of therapy to treat chronic HCV infection. Conditions required:
  - Detectable HCV RNA at 12 weeks post treatment
  - HCV genotype is the SAME before and after the INITIAL HCV treatment regimen
- **Reinfection**: Previous exposure to an HCV treatment regimen, which resulted in achievement of SVR, but now there is a new need for a course of therapy to treat chronic HCV infection. Conditions required:
  - Detectable HCV RNA > 12 weeks post treatment
  - HCV genotype is DIFFERENT after the INITIAL HCV treatment regimen
  - Current infection has been present 6 months, or greater

IX. REFERENCES

1. American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at http://www.hcvguidelines.org/. Accessed March 13, 2019.
2. Mavyret [package insert]. North Chicago, IL: AbbVie Inc., June 2021.
3. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc., March 2020.
4. Zepatier [package insert]. Whitehouse Station, NJ: Merck and Co., Inc., December 2021.
5. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc., April 2022.
6. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc., November 2019.

X. APPROVALS

Signature on file at JHHC

Date of Revision	Summary of Revision
04/01/2015	DHMH updates
07/01/2015	DHMH updates
08/15/2015	DHMH updates & addition of Daklinza & Technivie
08/19/2015	Addition of new drugs to market with DHMH requirements
03/21/2016	Updated Sovaldi, Harvoni & Daklinza criteria to include new genotypes. Added Zepatier to policy (reviewed at Jan 2017 P&T)
10/19/2016	Updated criteria for overview of Epclusa/Zepatier (reviewed at Jan.2017 P&T)
07/27/2017	Updated Exclusions policy regarding physician samples
10/18/2017	Updated criteria to include Vosevi/Mavyret and updated preferred formulary agent as Mavyret
11/01/2018	Updated criteria in accordance with new MDH guidance
07/01/2019	Updated criteria and removed Sovaldi and Daklinza as applicable drugs in accordance with new MDH policy (Reviewed at 4/17/19 P&T meeting, with an effective date of 7/1/2019)
07/15/2020	Updated criteria in accordance with new revised MDH policy (Reviewed at 7/15/2020 P&T meeting, with an effective date of 8/1/2020
01/08/2021	Updated criteria in accordance with revised MDH policy, and latest FDA-approved prescribing information
11/16/2021	Clarified chronicity definition and required evidence
12/30/2021	Removed on-treatment HCV-RNA lab result-related criteria in accordance with MDH criteria change effective 1/1/2022
02/17/2022	Clarified evidence of chronicity per updated MDH guidance
05/20/2022	Updated age restrictions for Mavyret, Zepatier, and Epclusa based on the latest FDA-approved prescribing information
07/28/2022	Updated criteria in accordance with revised MDH policy, and latest FDA-approved prescribing information

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