Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 direct-acting antiviral (DAA) Hepatitis C Agent when there is a record of a recent claim for another DAA Hepatitis C Agent in the point-of-sale online claims adjudication system (therapeutic duplication).

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. For a non-preferred DAA Hepatitis C Agent, **all** of the following:

   a. If genotyping is recommended by the American Association for the Study of Liver Diseases (AASLD), has documentation of genotype**,**

   b. Is prescribed a drug regimen that is consistent with U.S. Food and Drug Administration (FDA)-approved labeling, nationally recognized compendia, or peer-reviewed medical literature,

   c. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

   d. Has a cirrhosis assessment documented by a recent noninvasive test (e.g., blood test or imaging, a Fibroscan, FIB-4 calculation, or findings on physical examination),

   e. If the beneficiary has received prior treatment(s) for hepatitis C, has documentation of previous hepatitis C treatment regimens,

   f. 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,

   g. **One** of the following:

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

ii. Is currently receiving treatment with the same non-preferred Hepatitis C Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

2. For all other non-preferred Hepatitis C Agents, all of the following:

   a. Is being treated for a diagnosis that is indicated in the FDA-approved package labeling OR a medically accepted indication,
   b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   c. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   d. Has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines;

   AND

3. For therapeutic duplication, has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

   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 DAA Hepatitis C Agents will be for the full recommended duration of treatment based on package labeling or consensus treatment guidelines.

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HEPATITIS C AGENTS PRIOR AUTHORIZATION FORM

Office contact name/phone:		Prescriber name:		
LTC facility contact/phone:		State license #:	NPI:	
Total # pages:		Street address:		
Beneficiary name:		City/state/zip:		
Beneficiary ID#:	DOB:	Phone:	Fax:	
Requested drug #1:	Directions:	Qty:	☐ 8 weeks ☐ 16 weeks ☐ 12 weeks ☐ Other: _____	
Requested drug #2:	Directions:	Qty:	☐ 8 weeks ☐ 16 weeks ☐ 12 weeks ☐ Other: _____	
Is the beneficiary currently being treated with the requested drug(s)?	☐ Yes – Therapy start date: _____		☐ No	

SUBMIT DOCUMENTATION from the medical record for all items below.

For requests for NON-PREFERRED Hepatitis C Agents direct-acting antivirals (DAAs):

1. Documentation that the beneficiary tried and failed or has a contraindication or intolerance to the preferred Hepatitis C Agents. *(See the Preferred Drug List for the list of preferred Hepatitis C Agents at: https://papdl.com/preferred-drug-list.)*
2. Cirrhosis assessment documented by a recent noninvasive test and date of testing.
3. Genotype if one of the following (check the appropriate box for the beneficiary):

☐ The beneficiary is prescribed a non-pangenotypic regimen.
☐ The beneficiary is hepatitis C sofosbuvir-based, sofosbuvir-velpatasvir-voxilaprevir, or sofosbuvir plus glecaprevir-pibrentasvir treatment-experienced.
☐ The beneficiary has decompensated cirrhosis and is prescribed ledipasvir-sofosbuvir.
☐ The beneficiary is treatment-naïve (with cirrhosis) and prescribed sofosbuvir-velpatasvir.

4. RAS (resistance-associated substitutions) testing and date of testing if one of the following (check the appropriate box for the beneficiary):

☐ The beneficiary is genotype 1a and prescribed elbasvir-grazoprevir.
☐ The beneficiary is genotype 1a, treatment-experienced, and prescribed ledipasvir-sofosbuvir.
☐ The beneficiary is genotype 3, treatment-naïve (with cirrhosis) or treatment-experienced (without cirrhosis) and prescribed 12 weeks of sofosbuvir-velpatasvir.

For requests for THERAPEUTIC DUPLICATION of Hepatitis C Agents direct-acting antivirals (DAAs):

For a beneficiary taking more than 1 Hepatitis C Agents DAA product concomitantly:

☐ The beneficiary has a medical reason for concomitant use of the requested products that is supported by peer-reviewed medical literature or national treatment guidelines.

For requests for ALL OTHER NON-PREFERRED Hepatitis C Agents (e.g., Pegasys): Diagnosis: _____

☐ The beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to first line therapies.

ATTESTATION from the prescriber for one of the items below.

Check the appropriate box for the beneficiary.

☐ The beneficiary is hepatitis C treatment naïve.
☐ The beneficiary has been treated for hepatitis C with the following treatment regimen: _____

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: