



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR	EPCLUSA, SOFOSBUVIR- VELPATASVIR	43561		GPI-10 (1235990265)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 **AND** meet the following criterion?
 - The patient is 3 years of age or older

If yes, continue to #2.
If no, continue to #6.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet at least **ONE** of the following criteria?
 - The patient is currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, Aptivus (tipranavir)/ritonavir, topotecan, Sovaldi (sofosbuvir, as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
 - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have decompensated cirrhosis **AND** the requested medication will be used with ribavirin?

If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**

- **400mg-100mg tablets: #1 per day.**
- **200mg-50mg tablets: #1 per day.**
- **200mg-50mg pellets: #2 per day.**
- **150mg-37.5mg pellets: #1 per day.**

If no, continue to #5.

5. Does the patient meet **ONE** of the following criteria?

- Treatment naïve and genotype 1-6 infection
- Treatment experienced, genotype 1-6 infection, with prior treatment with one of the following: 1) peginterferon/ribavirin or 2) NS3 protease inhibitor triple therapy (Olysio [simeprevir], Incivek [telaprevir] or Victrelis [boceprevir] with peginterferon/ribavirin)
- Treatment experienced, genotype 1b or genotype 2 infection, with previous treatment with Sovaldi (sofosbuvir)-containing regimen (e.g., Sovaldi [sofosbuvir]/ribavirin with or without peginterferon or Sovaldi [sofosbuvir]/Olysio [simeprevir]) that does not include an NS5A inhibitor

If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**

- **400mg-100mg tablets: #1 per day.**
- **200mg-50mg tablets: #1 per day.**
- **200mg-50mg pellets: #2 per day.**
- **150mg-37.5mg pellets: #1 per day.**

If no, continue to #6.

6. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

If yes, **approve as indicated per guidance in AASLD/IDSA.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

- A. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
- B. You have chronic hepatitis C (type of liver inflammation) with genotype 1, 2, 3, 4, 5, or 6
- C. You are 3 years of age or older
- D. You have an HCV RNA level (amount of virus in your blood) within the past 6 months
- E. **If you have decompensated cirrhosis (type of liver condition), approval also requires:**
 - 1. The requested medication will be used with ribavirin
- F. **If you do not have cirrhosis (liver damage) OR you have compensated cirrhosis (type of liver condition), approval also requires ONE of the following:**
 - 1. You are treatment naive (never previously treated)
 - 2. You are treatment experienced (have previously been treated) with peginterferon/ribavirin or NS3 protease inhibitor triple therapy (type of hepatitis drug such as Olysio [simeprevir], Incivek [telaprevir] or Victrelis [boceprevir] with peginterferon/ribavirin)
 - 3. You have genotype 1b or genotype 2 infection AND you are treatment experienced with a Sovaldi (sofosbuvir)-containing regimen that does not include an NS5A inhibitor (type of hepatitis drug) such as Sovaldi (sofosbuvir)/ribavirin with or without peginterferon or Sovaldi (sofosbuvir)/Olysio (simeprevir)

Epclusa will not be approved if you meet any of the following:

- A. You are using any of the following medications with the requested agent: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, Aptivus (tipranavir)/ritonavir, topotecan, Sovaldi (sofosbuvir, as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
- B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epclusa.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed July 28, 2016.
- Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/23

Created: 07/16

Client Approval: 08/23

P&T Approval: 07/23