STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELBASVIR/GRAZOPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELBASVIR/ GRAZOPREVIR	ZEPATIER	43030		GPI-10 (1235990230)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, with genotype 1 or genotype 4 **AND** meet the following criterion?
   - The patient is 12 years of age or older OR weighs at least 30kg

   If yes, continue to #2.
   If no, continue to #8.

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 has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - The patient has moderate or severe hepatitis impairment (Child-Pugh B or C)
   - The patient is currently taking any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., Prezcobix, Prezista), lopinavir, saquinavir, Aptivus (tipranavir), cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, rosuvastatin at doses greater than 10mg daily, Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

   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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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has a contraindication to Epclusa (velpatasvir/sofosbuvir) AND Harvoni (ledipasvir/sofosbuvir)
   - The patient has failed a short trial with Epclusa (velpatasvir/sofosbuvir) or Harvoni (ledipasvir/sofosbuvir) (e.g., inability to tolerate, adverse effect early in therapy); (**NOTE:** An individual who has completed a full course of therapy with Epclusa [velpatasvir/sofosbuvir] or Harvoni [ledipasvir/sofosbuvir] that did not achieve SVR will not be approved.)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - Genotype 1a infection, treatment naïve, and NO baseline NS5A polymorphisms
   - Genotype 1a infection, previously treated with peginterferon/ribavirin, and NO baseline NS5A polymorphisms
   - Genotype 1b infection, treatment naive
   - Genotype 1b infection, previously treated with peginterferon/ribavirin
   - Genotype 4 infection, treatment naïve

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Is the requested medication being used with ribavirin and the patient meets **ONE** of the following criteria?
   - Genotype 1a infection, previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (e.g., Victrelis [boceprevir], Incivek [telaprevir], Olysio [simeprevir]) plus peginterferon/ribavirin)
   - Genotype 1b infection, previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (e.g., Victrelis [boceprevir], Incivek [telaprevir], Olysio [simeprevir]) plus peginterferon/ribavirin)

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #7.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

7. Is the requested medication being used with ribavirin and the patient meets **ONE** of the following criteria?
   - Genotype 1a infection, treatment naïve, and has baseline NS5A polymorphisms
   - Genotype 1a infection, previously treated with peginterferon/ribavirin, and has baseline NS5A polymorphisms
   - Genotype 4 infection, previously treated with peginterferon/ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #8.

8. 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: *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 for **ELBASVIR/GRAZOPREVIR (Zepatier)** 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 infection)
   C. You have genotype 1 or genotype 4 hepatitis C
   D. You are 12 years of age or older OR weigh at least 30kg
   E. You have an HCV RNA level (amount of virus in your blood) within the past 6 months
   F. You have tried a short course of Epclusa (velpatasvir/sofosbuvir) or Harvoni (ledipasvir/sofosbuvir) OR have a contraindication (harmful for) to both. Patients with previous failure of a full treatment of Epclusa (velpatasvir/sofosbuvir) or Harvoni (ledipasvir/sofosbuvir) will not be approved
   G. If you have genotype 1a infection, we require testing for baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein)

   (Denial text continued on next page)

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

H. Ribavirin use is required if you meet ANY of the following:
   1. You have genotype 1a or 1b infection and were previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (such as Victrelis [boceprevir], Incivek [telaprevir], Olysio [simeprevir]) plus peginterferon/ribavirin
   2. You have genotype 1a infection, are treatment naive, and have baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein)
   3. You have genotype 1a infection, were previously treated, and have baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein)
   4. You have genotype 4 infection and were previously treated

I. Treatment experienced patients will be approved per product labeling (previous failure of peginterferon/ribavirin for genotype 1a, 1b or 4; previous failure of HCV protease inhibitor triple therapy regimen for genotype 1a or 1b infection)

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

A. You are using any of the following interacting medications at the same time while on Zepatier (elbasvir/grazoprevir): phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, Aptivus (tipranavir), cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, rosuvastatin at doses greater than 10mg daily, Sovaldi (sofosbuvir), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
B. You have moderate or severe liver impairment (Child-Pugh B or C: type of liver condition)
C. 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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ELBASVIR/GRAZOPREVIR

RATIONALE

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

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 7, 2017.
- Zepatier [Prescribing Information]. Rahway, NJ: Merck; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 02/16
Client Approval: 08/23
P&T Approval: 07/23