GUIDELINES FOR USE

1. Is the patient at least 18 years old?
   - If yes, continue to #2.
   - If no, do not approve.
   
   **DENIAL TEXT:** See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of chronic hepatitis C, with genotype 1, 2, 3, 4, 5, or 6?
   - 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 have a chronic HCV infection documented by at least **ONE** detectable HCV RNA level within the last 6 months?
   - If yes, continue to #4.
   - If no, do not approve.
   
   **DENIAL TEXT:** See the denial text at the end of the guideline.

4. Does the patient have evidence of fibrosis stage 3 or 4 as determined by any **ONE** of the following?
   - Metavir score F3 or F4 from liver biopsy
   - APRI score above 1.5
   - Radiological Imaging consistent with cirrhosis
   - Evidence from physical exam and clinical findings consistent with cirrhosis
   - Fibroscan score of 9.5kPa or higher
   - FibroTest result of 0.58 or higher

   - If yes, continue to #6.
   - If no, continue to #5.

   **CONTINUED ON NEXT PAGE**
5. Does the patient have Metavir Stage 2 with another condition listed as 'high priority' or 'highest priority' for treatment, such as liver transplant recipient, severe extra-hepatic hepatitis C, other co-existing liver disease such as non-alcoholic steatohepatitis, debilitating fatigue, porphyria cutanea tarda, diabetes type 2, hepatitis B or HIV coinfection; (NOTE: Metavir Stage 2 can be determined by any one of the following)?

• Metavir score F2 from liver biopsy
• APRI score of 0.78-1.49
• Fibroscan score of 7.65kPa-9.49
• FibroTest result of 0.5-0.57

If yes, continue to #6.
If no, do not approve.

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

6. Does the patient meet ALL of the following criteria?

• Genotype 1 HCV infection
• Treatment naïve
• No cirrhosis
• No HIV co-infection
• Pre-treatment HCV RNA level < 6 million IU/mL

If yes, continue to #7.
If no, continue to #8.

7. Has the patient had a trial of Harvoni 8-week regimen, or does the patient have a contraindication to Harvoni?

If yes, continue to #8
If no, do not approve.

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

8. Does the patient have severe renal impairment (estimated glomerular filtration rate (GFR) less than 30mL/min/1.73m²) or end stage renal disease requiring dialysis?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
If no, continue to #9.

CONTINUED ON NEXT PAGE
SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

9. Is the patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model?
   
   If yes, continue to #10.
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

10. Is the patient currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan?

   If yes, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.
   If no, continue to #11.

11. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)?

   If yes, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.
   If no, continue to #12.

12. Does the patient have decompensated cirrhosis?

   If yes, continue to #13.
   If no, **approve for 12 weeks by HICL for #1 tablet per day.**

13. Is the requested medication being used with ribavirin?

   If yes, **approve for 12 weeks by HICL for #1 tablet per day.**
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

**CONTINUED ON NEXT PAGE**
DENIAL TEXT: Our guideline for SOFOSBUVIR/VELPATASVIR requires a diagnosis of hepatitis C. In addition, the following criteria must also be met:

- Patient has genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Patient is at least 18 years old
- Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Patient has evidence of fibrosis stage 3 or 4 (Metavir F3 or F4 equivalent) or Metavir F2 with another condition listed as 'high priority' or 'highest priority' for treatment, such as liver transplant recipient, severe extra-hepatic hepatitis C, other co-existing liver disease such as non-alcoholic steatohepatitis, debilitating fatigue, or porphyria cutanea tarda, diabetes type 2, hepatitis B or HIV coinfection
- Documentation of HCV infection (e.g., at least ONE detectable HCV RNA level within the last 6 months)
- For patients with decompensated cirrhosis, the patient must be using a ribavirin-containing regimen
- Treatment naïve patients with genotype 1 infection and without cirrhosis that have a pretreatment HCV RNA level less than 6 million IU/mL must have a trial of Harvoni 8-week regimen or a contraindication to Harvoni

The medication will not be approved for the following patients:

- Patient using any of the following medications concurrently while on Epclusa: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
- Patient with severe renal impairment (estimated glomerular filtration rate (GFR) less than 30mL/min/1.73m²) or end stage renal disease requiring hemodialysis
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

RATIONALE
Ensure appropriate utilization of Epclusa (sofosbuvir/velpatasvir).

FDA APPROVED INDICATIONS
For the treatment of chronic hepatitis C genotype 1-6 infection in adults

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SOFOSBUVIR/VELPATASVIR

FDA APPROVED DOSAGE

- One 400mg/100mg tablet taken once daily with or without food.
  Duration of therapy is as follows:

<table>
<thead>
<tr>
<th>Patient type</th>
<th>Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>No cirrhosis or compensated cirrhosis (Child-Pugh A)</td>
<td>Epclusa for 12 weeks</td>
</tr>
<tr>
<td>Decompensated cirrhosis (Child-Pugh B or C)</td>
<td>Epclusa + ribavirin for 12 weeks</td>
</tr>
</tbody>
</table>

OTHER INFORMATION

Epclusa is the first single tablet, all-oral combination therapy approved to treat chronic hepatitis C, genotypes 1-6. It is a combination of sofosbuvir, a NS5B polymerase inhibitor (currently also available as a single ingredient medication under brand Sovaldi), with velpatasvir, a new NS5A inhibitor. Potential advantages for Epclusa include once daily dosing, excellent tolerability, improved SVR rates in difficult-to-treat patients including decompensated cirrhosis, and it is the first agent to offer an all-oral, interferon-free, ribavirin-free single-tablet regimen for genotypes 2 and 3.

EFFICACY

The efficacy of Epclusa was evaluated in four phase 3 clinical trials with over 1500 patients. The primary efficacy endpoint for all four studies was a 12-week sustained virologic response (SVR12), defined as HCV RNA below the lower limit of quantification (<15IU/mL), at 12 weeks after the end of treatment.

CONTINUED ON NEXT PAGE
### SOFOSBUVIR/VELPATASVIR

#### EFFICACY (CONTINUED)

Table 1: Major phase III clinical trials for Epclusa [adapted from Epclusa prescribing information]

<table>
<thead>
<tr>
<th>Study</th>
<th>Clinical trial design</th>
<th>Treatment and comparator groups</th>
<th>Patient population</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTRAL-1</td>
<td>Randomized, double-blind, placebo-controlled trial</td>
<td>Epclusa 12 weeks (n=624) and placebo 12 weeks (n=116)</td>
<td>Treatment naïve and treatment experienced patients with genotype 1, 2, 4, 5 or 6, without cirrhosis or with compensated cirrhosis (19% had cirrhosis)</td>
</tr>
<tr>
<td>ASTRAL-2</td>
<td>Randomized, open-label study</td>
<td>Epclusa 12 weeks (n=134) and Sovaldi/ribavirin for 12 weeks (n=132)</td>
<td>Treatment naïve and treatment experienced patients with genotype 2 infection, without cirrhosis or with compensated cirrhosis (14% had cirrhosis)</td>
</tr>
<tr>
<td>ASTRAL-3</td>
<td>Randomized, open-label study</td>
<td>Epclusa 12 weeks (n=277) and Sovaldi/ribavirin for 24 weeks (n=275)</td>
<td>Treatment naïve and treatment experienced patients with genotype 3 infection, without cirrhosis or with compensated cirrhosis (30% had cirrhosis)</td>
</tr>
<tr>
<td>ASTRAL-4</td>
<td>Randomized, open-label study</td>
<td>Epclusa 12 weeks (n=90), Epclusa/ribavirin for 12 weeks (n=87), and Epclusa for 24 weeks (n=90)</td>
<td>Treatment naïve and treatment experienced patients with genotype 1, 2, 3, 4, 5 or 6 infection, with decompensated cirrhosis (Child-Pugh B)</td>
</tr>
</tbody>
</table>

CONTINUED ON NEXT PAGE
SOFOSBUVIR/VELPATASVIR

EFFICACY (CONTINUED)

Efficacy - Patients with HCV genotype 1, 2, 4, 5 or 6 infection (no cirrhosis or compensated cirrhosis)
The ASTRAL-1 study, a randomized, double-blind, placebo-controlled study, compared a 12-week Epclusa regimen with 12 weeks of placebo in 740 patients. Patients had genotype 1, 2, 4, 5 or 6 chronic HCV infection, without cirrhosis (81%) or with compensated cirrhosis (19%). Due to a small number of patients with genotype 5 infection, all patients with genotype 5 were assigned to Epclusa treatment, while patients with other genotypes were randomized 5:1 to Epclusa or placebo for 12 weeks. Patient characteristics included median age of 56 (range 18-82 years); 60% male; 79% Caucasian; 9% of African descent; 21% with baseline body mass index (BMI) of 30kg/m² or greater; and 53% were infected with genotype 1 infection, 17% with genotype 2 infection, 19% with genotype 4 infection, 5% with genotype 5 infection and 7% with genotype 6 infection. The majority of patients were treatment naïve. Among the 32% of study patients who were treatment-experienced, most had previously used a regimen with peginterferon/ribavirin. Other previous regimens used included HCV protease inhibitor with peginterferon/ribavirin or a non-pegylated interferon with or without ribavirin. Patients with previous failure of NS5B inhibitor or a NS5A inhibitor were excluded from the study. The overall SVR rates was 99%, with SVR rates ranging from 97% to 100%. SVR rates were 100% for patients with genotype 2, genotype 4 and genotype 6 infection.

Table 2: Virologic outcomes by HCV genotype in patients receiving Epclusa in the ASTRAL-1 clinical trial, 12 weeks after treatment [from Epclusa prescribing information]

<table>
<thead>
<tr>
<th>HCV Genotype</th>
<th>Total (N=624)</th>
<th>GT-1 (N=210)</th>
<th>GT-1b (N=118)</th>
<th>Total (N=328)</th>
<th>GT-2 (N=104)</th>
<th>GT-4 (N=116)</th>
<th>GT-5 (N=35)</th>
<th>GT-5 (N=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVR12</td>
<td>99% (618/624)</td>
<td>98% (208/210)</td>
<td>99% (117/118)</td>
<td>98% (323/328)</td>
<td>100% (104/104)</td>
<td>100% (119/119)</td>
<td>97% (34/35)</td>
<td>100% (41/41)</td>
</tr>
<tr>
<td>Outcome for Subjects without SVR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On-Treatment Virologic Failure</td>
<td>0/624</td>
<td>0/210</td>
<td>0/118</td>
<td>0/328</td>
<td>0/104</td>
<td>0/116</td>
<td>0/35</td>
<td>0/41</td>
</tr>
<tr>
<td>Relapse</td>
<td>&lt;1% (2/623)</td>
<td>&lt;1% (1/209)</td>
<td>&lt;1% (1/118)</td>
<td>&lt;1% (2/327)</td>
<td>0/104</td>
<td>0/116</td>
<td>0/35</td>
<td>0/41</td>
</tr>
<tr>
<td>Other</td>
<td>1% (4/624)</td>
<td>1% (3/210)</td>
<td>0/118</td>
<td>1% (3/328)</td>
<td>0/104</td>
<td>0/116</td>
<td>3% (1/35)</td>
<td>0/41</td>
</tr>
</tbody>
</table>

GT = genotype; no subjects in the placebo group achieved SVR12.
a. The denominator for relapse is the number of subjects with HCV RNA <LLQ at their last on-treatment assessment.
b. Other includes subjects who did not achieve SVR and did not meet virologic failure criteria.

CONTINUED ON NEXT PAGE
SOFOSBUVIR/VELPATASVIR

EFFICACY (CONTINUED)

Patients with HCV genotype 2 infection (no cirrhosis or compensated cirrhosis)
The ASTRAL-2 study, a randomized, open-label study, compared the efficacy of a 12-week Epclusa regimen with 12 weeks of Sovaldi/ribavirin in 266 patients with genotype 2 infection. Patients were randomized to treatment groups in a 1:1 ratio. The majority of patients had no cirrhosis (86%); 14% had compensated cirrhosis. Patient characteristics included median age of 58 years (range 23 to 81 years), 59% male, 88% Caucasian, 7% of African descent, 33% had a baseline BMI of at least 30kg/m², and 15% were treatment-experienced. Overall SVR rate was 99% for patients with genotype 2 infection taking Epclusa for 12 weeks, and 94% for those taking Sovaldi/ribavirin for 12 weeks. SVR rates were lower for treatment-experienced patients and those with compensated cirrhosis than for treatment-naïve patients and those without cirrhosis, respectively. Relapse rates were higher for those using the Sovaldi/ribavirin regimen (5%) than for the Epclusa regimen (0%).

Patients with HCV genotype 3 infection (no cirrhosis or compensated cirrhosis)
The ASTRAL-3 study, a randomized, open-label study, compared the efficacy of a 12-week Epclusa regimen with 24 weeks of Sovaldi/ribavirin in 552 patients with genotype 3 infection. Patients were randomized to treatment groups in a 1:1 ratio. Patient characteristics included median age of 52 years (range 19 to 76 years), 62% male, 89% Caucasian, 9% of Asian descent, 20% had a baseline BMI of at least 30kg/m², 30% had compensated cirrhosis, and 26% were treatment-experienced.

Overall SVR rate was 95% for patients with genotype 3 infection taking Epclusa for 12 weeks, and 80% for those taking Sovaldi/ribavirin for 24 weeks. In both treatment groups SVR rates were lower for treatment-experienced patients and those with compensated cirrhosis than for treatment-naïve patients and those without cirrhosis, respectively. Relapse rates were higher for those using the Sovaldi/ribavirin regimen (14%) than for the Epclusa regimen (4%).

CONTINUED ON NEXT PAGE
Table 3: SVR12 in patients with genotype 3 HCV in the ASTRAL-3 clinical trial
[from Epclusa prescribing information]

<table>
<thead>
<tr>
<th></th>
<th>EPCLUSA 12 Weeks</th>
<th>SOF + RBV 24 Weeksa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment-Naïve (N=206)</td>
<td>Treatment-Experienced (N=71)</td>
</tr>
<tr>
<td>Without cirrhosis</td>
<td>98% (160/163)</td>
<td>94% (31/33)b</td>
</tr>
<tr>
<td>With compensated cirrhosis</td>
<td>93% (40/43)</td>
<td>89% (33/37)</td>
</tr>
</tbody>
</table>

SOF = sofosbuvir; RBV = ribavirin.
a. Five subjects with missing cirrhosis status in the SOF + RBV 24-week group were excluded from this subgroup analysis.
b. One treatment-experienced subject without cirrhosis treated with EPCLUSA had genotype 1a HCV infection at failure, indicating HCV re-infection, and is therefore excluded from this analysis.

Patients with decompensated cirrhosis
The ASTRAL-4 study, a randomized, open-label study of 267 patients with decompensated cirrhosis (Child-Pugh B) with genotype 1, 2, 3, 4, 5 or 6 HCV infection, compared Epclusa for 12 weeks (n=90), Epclusa with ribavirin for 12 weeks (n=87), and Epclusa for 24 weeks (n=90). Patient characteristics included median age of 59 years (range 40 to 73 years), 70% male, 90% Caucasian, 6% of African descent, 42% had a baseline BMI of at least 30kg/m², 95% had a Model for End Stage Liver Disease (MELD) score of 15 or less at baseline, and 55% were treatment experienced. The majority had genotype 1 infection (78%), and 4% had genotype 2, 15% had genotype 3, 3% had genotype 4, and less than 1% (1 participant) had genotype 6; no participants had genotype 5 infection. Although all patients enrolled were determined to have Child-Pugh B cirrhosis at baseline, 6% had Child-Pugh A and 4% had Child-Pugh C cirrhosis on the first day of treatment.

CONTINUED ON NEXT PAGE
SOFOSBUVIR/VELPATASVIR

EFFICACY (CONTINUED)

Table 4: Virologic outcomes in patients with decompensated cirrhosis in the ASTRAL-4 clinical trial
[from Epclusa prescribing information]

<table>
<thead>
<tr>
<th></th>
<th>Epclusa + ribavirin for 12 weeks (n=87)</th>
<th>Virologic Failure (relapse and on-treatment failure)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall SVR 12</td>
<td>94% (82/87)</td>
<td>3% (3/87)</td>
</tr>
<tr>
<td>Genotype 1</td>
<td>96% (65/68)</td>
<td>1% (1/68)</td>
</tr>
<tr>
<td>Genotype 1a</td>
<td>94% (51/54)</td>
<td>2% (1/54)</td>
</tr>
<tr>
<td>Genotype 1b</td>
<td>100% (14/14)</td>
<td>0% (0/14)</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>100% (4/4)</td>
<td>Not available</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>85% (11/13)</td>
<td>15% (2/13)</td>
</tr>
<tr>
<td>Genotype 4</td>
<td>100% (2/2)</td>
<td>Not available</td>
</tr>
</tbody>
</table>

SAFETY

When Epclusa is prescribed with ribavirin, prescribers must also consider contraindications, warnings, and precautions associated with ribavirin therapy. The Epclusa regimen with ribavirin is contraindicated in patients for whom ribavirin is contraindicated.

For patients using a 12-week regimen of Epclusa without ribavirin, the most common adverse reactions reported in clinical trials (10% or greater incidence) include headache and fatigue. Less common adverse events that occurred more often for those treated with Epclusa than for those treated with placebo in the ASTRAL-1 study include rash (2% incidence in Epclusa treatment group) and depression (1% incidence in Epclusa treatment group). In the ASTRAL-4 study patients with decompensated cirrhosis using Epclusa with ribavirin for 12 weeks most commonly experienced (adverse effects with 10% or greater incidence) fatigue (32%), anemia (26%), nausea (15%), headache (11%), insomnia (11%), and diarrhea (10%).

CONTINUED ON NEXT PAGE
**Table 5: Laboratory Abnormalities** [from Epclusa prescribing information]

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Epclusa 12 weeks</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipase elevations &gt;3x upper limit of normal (ULN), ASTRAL-1 study</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Lipase elevations &gt;3x upper limit of normal (ULN), ASTRAL-2 and ASTRAL-3 studies</td>
<td>6%</td>
<td>3%</td>
</tr>
<tr>
<td>Lipase elevations &gt;3x upper limit of normal (ULN), ASTRAL-4 study</td>
<td>2% (patients used Epclusa + ribavirin)</td>
<td>N/A</td>
</tr>
<tr>
<td>Asymptomatic creatine kinase elevations 10x ULN or greater, ASTRAL-1 study</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>Asymptomatic creatine kinase elevations 10x ULN or greater, ASTRAL-2 and ASTRAL-3 studies</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Asymptomatic creatine kinase elevations 10x ULN or greater, ASTRAL-4 study</td>
<td>1% (patients used Epclusa + ribavirin)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

No dosage adjustment is necessary for patients with mild, moderate or severe hepatic impairment (Child Pugh Class A, B or C). The safety and efficacy of Epclusa have not been studied in patients with severe renal impairment (estimated glomerular filtration rate (GFR) less than 30mL/min/1.73m²) for dose adjustment is available for patients with severe renal impairment or for those using hemodialysis. Patients with renal impairment using an Epclusa regimen in combination with ribavirin may require a reduced ribavirin dose.
SAFETY (CONTINUED)

Velpatasvir is an inhibitor of drug transporters P-glycoprotein (P-gp), breast cancer resistance protein, OATP1B1, OATP1B3 and OATP2B1. Drug interactions with Epclusa include medications that are P-gp inducers such as rifampin and St John’s wort. The following medications may decrease the concentrations of Epclusa: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, St. John’s Wort, efavirenz-containing HIV regimens, or tipranavir/ritonavir; concurrent administration of these agents with Epclusa is not recommended. The following medications interact with Epclusa and an increase in their concentration may occur with coadministration with Epclusa: atorvastatin, rosuvastatin (doses above 10mg), digoxin, tenofovir DF, and topotecan; concurrent administration of Epclusa with rosuvastatin (doses above 10mg) or topotecan is not recommended.

The solubility of velpatasvir, a component of Epclusa, decreases as pH increases. Drugs that may increase gastric pH, such as antacids, H2 blockers, and proton pump inhibitors could decrease concentrations of velpatasvir. If the patient continues to use these medications while taking Epclusa, the manufacturer recommends the following:

- Patients using antacids while taking Epclusa should separate administration of the two medications by at least 4 hours.
- Patients using H2 blockers should use a dose equivalent to famotidine 40mg twice daily or less.
- Co-administration of proton pump inhibitors is not recommended. However, if medically necessary, patients using proton pump inhibitors should use a dose equivalent to omeprazole 20mg daily or less, and Epclusa dose should be taken with food and at least 4 hours prior to omeprazole (use with other proton pump inhibitors has not been studied).

Coadministration of Epclusa and amiodarone could lead to serious symptomatic bradycardia and is not recommended. Patients using digoxin while taking Epclusa may experience an increase in digoxin levels. Therapeutic concentration monitoring of digoxin levels while on Epclusa is recommended.

The safety and efficacy of Epclusa has not been evaluated in the pediatric population. Clinical trials of Epclusa included 156 participants age of 65 and older (12% of participants in Epclusa phase 3 trials). No overall difference in safety or efficacy of Epclusa in geriatric patients was found and no dosage adjustment of Epclusa in geriatric patients is warranted. However, greater sensitivity in some older individuals cannot be ruled out.

There are no adequate human studies on the safety of Epclusa use in pregnant humans; however, animal studies indicate that no adverse developmental effects were observed with Epclusa at doses up to 31 times the recommended human dose. However, if Epclusa is used in combination with ribavirin, the combination regimen is contraindicated in pregnant women and in men with pregnant female partners due to ribavirin-associated risks of use during pregnancy.

CONTINUED ON NEXT PAGE
SOFOSBUVIR/VELPATASVIR

SAFETY (CONTINUED)

While it is not known whether Epclusa is present in human breast milk, a sofosbuvir metabolite (GS-331007) was present in the milk of lactating rats administered sofosbuvir, but was not found to affect the growth or development of nursing rat pups. Similarly, velpatasvir has been detected in the milk of lactating rats and the plasma of nursing pups, but was not found to affect nursing rat pups. When considering the decision to breastfeed, the benefits of breastfeeding must be weighed against the risks of any potential adverse effects on the breastfed child from Epclusa.

REFERENCES