CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Zepatier (grazoprevir/elbasvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Mavyret and Sofosbuvir/velpatasvir (generic for Epclusa) QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Zepatier (grazoprevir/elbasvir) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:
Member must meet all criteria below Step 1 and Step 2 and Step 3.

Step 1 (evaluation of member's readiness):

1. Member must be 18 years of age or older; AND
2. Member must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy (laboratory documentation required for month 1 and for month 6 and for one additional month between month 2-5); AND
3. Member must meet kidney function as indicated in package labeling for product (No dosage adjustment of Zepatier is recommended in members with any degree of renal impairment including members receiving hemodialysis. Renal dosage adjustment needed in members on ribavirin with CrCl ≤ 50 mL per minute); AND
4. Member must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information (Zepatier and ribavirin combination regimen is contraindicated in members for whom ribavirin is contraindicated; see additional notes in Appendix[1]); AND
5. Member must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the member attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria); AND

Step 2 (clinical assessment of disease):

6. Member has tried and failed courses of treatment with Sofosbuvir/velpatasvir (generic for Epclusa) and Mavyret (Dates and HCV RNA values must be documented in chart notes); AND
7. Member has confirmation of chronic hepatitis C (CHC):
   a) Hepatitis C Virus (HCV) antibody test reactive; AND
   b) Provide HCV RNA load measured within 90 days prior to starting DAA therapy; AND
   c) Specify the Genotype (choose one of the following statuses):

i) Adults with genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis. If HCV genotype 1a with cirrhosis, consider testing for the presence of virus with NS5A resistance-associated polymorphisms; AND

8. Member has documented progression of disease:
   a) Document the degree of liver fibrosis:
      i) Liver biopsy; OR
      ii) One radiological and one serological test; AND
   b) If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score (Daklinza is contraindicated in members with moderate or severe hepatic impairment (Child-Pugh B or C)); AND
   c) Zepatier must be used in combination with ribavirin if member has NS5A resistance-associated polymorphisms or if member is peginterferon alfa and ribavirin-experienced. If ribavirin ineligible must submit documentation of ONE of the following results obtained within the past month:
      i) History of severe or unstable cardiac disease
      ii) Pregnant women and men with pregnant partners
      iii) Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
      iv) Hypersensitivity to ribavirin
      v) Baseline platelet count < 70,000 cells/mm^3
      vi) ANC < 1500 cells/mm^3
      vii) Hb < 12 gm/dL in women or < 13 g/dL in men; AND
9. Document that member does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions; AND
10. Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (member will not be approved if any other HCV treatments have been used in the last 6 months); AND

Step 3 (Direct Acting Antivirals (DAA) conditions for coverage):

11. Medication must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist; AND
12. Member's documented HCV RNA testing is required every 4 weeks and submitted with chart notes; AND
13. Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs); AND
14. Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved with duration of approval based upon guidelines. Regimens listed as not recommended will not be approved.
15. **Dosage allowed:** One tablet once daily for 12 weeks OR one tablet once daily with ribavirin for 16 weeks, see Appendix[2] for details.

If member meets all the requirements listed above, the medication will be approved for 12-16 weeks, see Appendix[2] below.

For **reauthorization**:

1. Zepatier will not be reauthorized.

CareSource considers Zepatier (grazoprevir/elbasvir) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Zepatier created. Alternative products were indicated. Hep B test requirement was added. Drug and alcohol screens for 3 consecutive months required for all regardless of abuse history. Evidence of liver fibrosis exceptions was expanded.

	Reauthorization requirement of 2 consecutive values of HCV RNA ≥25 IU per mL during the post-treatment period and documented reason of treatment failure were added.
06/08/2017	Fibrosis stage 2 and above covered.
11/22/2017	Medication status changed to non-preferred. Substance abuse program information is no longer required. Trial of preferred agent is required. Reauthorization criteria were removed. Criterion on absence of moderate to severe liver impairment was added.
12/07/2017	Criterion of "life expectancy not less than one year due to non-liver related comorbidities" removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.
12/17/2018	Criteria changed per Ohio Department of Medicaid requirement. Minimum of 3 months of "drug/alcohol free period" criterion changed to 6 months; no fibrosis score required, but documentation of degree liver fibrosis changed; kidney function and clinical interactions addressed; HCV RNA load measurement prior to starting DAA therapy changed from "within 6 months" to "within 90 days"; cirrhosis score required; prescribers specialty changed; HCV RNA testing is now required every 4 weeks.
05/01/2019	Sofosbuvir/velpatasvir (generic for Epclusa) trial added.

References:

1. Zepatier [package insert]. Merck Sharp & Dohme Corp: Whitehouse Station, NJ; February, 2017.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017. Available at: https://www.hcvguidelines.org/.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 07/01/2019
Revised date: 05/01/2019

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Appendix. Current Medication List and Treatment Duration

[1]Current medication list does NOT include: carbamazepine, phenytoin, rifampin, St. John's Wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, bosentan, tacrolimus, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (disoproxil fumarate or alafenamide), modafinil, daily doses exceeding the following: atorvastatin 20 mg or rosuvastatin 10 mg.

[2]Treatment Duration

Genotype and Population	Treatment	Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV experienced[1] without baseline NS5A polymorphisms[2]	Zepatier	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV experienced[1] with baseline NS5A polymorphisms[2]	Zepatier + ribavirin	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV experienced[1]	Zepatier	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced[3]	Zepatier + ribavirin	12 weeks
Genotype 4: Treatment-naïve	Zepatier	12 weeks
Genotype 4: PegIFN/RBV-experienced[1]	Zepatier + ribavirin	16 weeks

[1]Peginterferon alfa + ribavirin.
[2]Polymorphisms at amino acid positions 28, 30, 31, or 93.
[3]Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.