PRIOR AUTHORIZATION PROTOCOL FOR HEPATITIS C TREATMENT

MAVYRET™ (Glecaprevir/Pibrentasvir)-PREFERRED AGENT

VOSEVI ™ (sofosbuvir/ velpatasvir/voxilaprevir)
EPCLUSA® (sofosbuvir/velpatasvir)
ZEPATIER® (elbasvir/grazoprevir)
HARVONI™ (ledipasvir/sofosbuvir)
DAKLINZA™ (Daclatasvir)
TECHNIVIE™ (Ombitasvir, paritaprevir, ritonavir)
VIEKIRA PAK™/VIEKIRA XR™ (Ombitasvir/paritaprevir/ritonavir/dasabuvir)
OLYSIO™ (simeprivir)
SOVALDI ™ (sofosbuvir)
PEG-INTRON™/ PEGASYS ™ (peginterferon alfa-2a)
RIBAVIRIN tablets or capsules
OR ANY OTHER NEWLY MARKETED AGENT for treatment of Hepatitis C

Where applicable and appropriate: MAVYRET (Glecaprevir/Pibrentasvir) is the PREFERRED AGENT for Hepatitis C requests unless a documented medical reason has been provided (intolerance, hypersensitivity, contraindication, etc.) why the member is not able to use Mavyret.

Initial requests must meet ALL of the following requirements:

1. Request must be for an appropriate FDA approved/AASLD guideline recommended indication, at an approved dose and duration, and for appropriate member (e.g. age/weight)
2. Provider attests that member does not have limited life expectancy of less than 12 months
3. Provider attests that member has been screened for Hepatitis B (HBV) and human immunodeficiency virus (HIV)
4. Provider attests that all potential drug interactions with concomitant medications have been addressed (including discontinuation of the interacting drug, dose reduction, or counseling of the member of the risks associated with the use of both medications)
5. Provider attests that member does not have current issues with compliance
6. Provider attests that member is not actively abusing drugs and/or alcohol **AND** the provider has received attestation from the member that he/she is not actively abusing drugs and/or alcohol.
7. Provider attests that member is committed to treatment plan, including lab monitoring and SVR12 lab testing will be completed and submitted to health plan
8. Member has **ONE** of the following:
    - History of liver transplant (include date **NOTE: does not require a certain level of fibrosis**)
    - Is HIV or HBV co-infected
    - Serious extrahepatic manifestations of Hepatitis C such as leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia
    - A Metavir fibrosis score of F3 or greater documented by liver biopsy, FibroSure/FibroTest or with sheer wave elastography (kPa>8.7)
    - Physical findings consistent with substantial or advanced fibrosis or cirrhosis
        - Hospitalization within the past 12 months for a condition attributed to hepatic cirrhosis, OR
        - History of hepatic encephalopathy requiring medication management and/or hospitalization within the past 12 months, OR

- History of portal hypertension as demonstrated by variceal bleeding or radiographic evidence or Transjugular Intrahepatic Portsystemic Shunt (TIPS) procedure

9. The following lab testing is required before treatment (copies of labs required)
    - Genotype (and subtype if provided)
    - RASs (resistance-associated substitutions, previously called RAVs) testing for Zepatier 1a requests or as indicted in treatment guidelines

    The following lab testing is required within **3 months** of starting therapy:
    - Detectable HCV RNA viral load
    - ALT/AST
    - GFR
    - INR
    - CBC (only if regimen contains ribavirin and hemoglobin must be at least 10g/dL)
    - Pregnancy test (**within 1 month** for regimens that contain ribavirin and the member is of child bearing age)
10. If member is cirrhotic, documentation of Child Turcotte Pugh Class (Class A, Class B, Class C)
11. The member will be referred to participate in Hepatitis C education and counseling program provided by the health plan
12. All approvals are for 28 days supply (see treatment summary that follows), and will be consistent with labeling or current guidelines, and are subject to change as guidelines are updated.

TREATMENT SUMMARY

Treatment Naive			
Genotype	**Treatment Option**	**Duration**	
		No Cirrhosis	**Compensated Cirrhosis (Child-Pugh A)**
1,2,3,4,5 or 6	**Mavyret**	**8 weeks**	**12 weeks**
1,2,3,4,5 or 6	Epclusa * ***ONLY if medical reason provided that member is unable to use Mavyret**	12 weeks	12 weeks

Treatment Experienced *Mavyret can **NOT** be used if previously treated with Zepatier/Technivie/Viekira or Viekira XR*			**Duration**	
Genotype	**Failed Regimen**	**Treatment Option**	**No Cirrhosis**	**Compensated Cirrhosis (Child-Pugh A)**
Genotype 1	Harvoni **OR** Epclusa **OR** Sovaldi/Daklinza	**Mavyret**	**16 weeks**	**16 weeks**
Genotype 1	Peg/Ribavirin with Olysio, Incivek or Victrelis **OR** Sovaldi/Olysio	**Mavyret**	**12 weeks**	**12 weeks**

Genotype 1, 2, 4, 5 or 6	Peg/Riba **OR** Sovaldi/Peg/Ribavirin **OR** Sovaldi/Ribavirin	**Mavyret**	**8 weeks**	**12 weeks**
Genotype 3	Peg/Riba **OR** Sovaldi/Peg/Ribavirin **OR** Sovaldi/Ribavirin	**Mavyret**	**16 weeks**	**16 weeks**
Genotype 1, 2,3,4,5 or 6	A regimen containing Daklinza* **OR** Zepatier **OR** Viekira/Viekira XR/Technivie **OR** Harvoni * **OR** Epclusa*	Vosevi* **Must have documented reason why unable to use Mavyret for Genotype 1*	12 weeks	12 weeks
Genotype 1a or 3	Sovaldi/Peg/Riba* **OR** Sovaldi/Olysio* **OR** Sovaldi/Ribavirin*	Vosevi * **Must have documented reason why unable to use Mavyret*	12 weeks	12 weeks

Unique patient populations (e.g. Decompensated Cirrhosis, Post-Transplant, etc. not addressed in previous tables)

Decompensated Cirrhosis (Child-Pugh B or C)	Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ **NOTE:** If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret
Post-Transplant	Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ **NOTE:** If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret
Hepatocellular Carcinoma	**NOTE:** Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ *If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret
Pediatrics	Refer to current AASLD guidelines @ http://www.hcvguidelines.org/ *If Mavyret is a recommended treatment option it is preferred unless medical reason provided that member is unable to use Mavyret

Patients with mild, moderate or severe renal impairment, including those requiring hemodialysis

Genotype	Treatment Option	Duration	
		No Cirrhosis	**Compensated Cirrhosis (Child-Pugh A)**
1,2,3,4,5 or 6	**Mavyret**	**8 weeks-16 weeks** Dependent on treatment history, GT-refer to package insert/guidelines	**12 weeks-16 weeks** Dependent on treatment history, GT-refer to package insert/guidelines
1 or 4	Zepatier* RAV testing required for GT1a ***ONLY if medical reason provided that member is unable to use Mavyret**	12 weeks-16** **Dependent on RAV testing and previous treatment history-refer to package insert/guidelines	12 weeks-16** **Dependent on RAV testing and previous treatment history-refer to package insert/guidelines

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