Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 17, 2017 March 2, 2017, March 9, 2017, March 14, 2017, March 20, 2017, May 1, 2017, February 16, 2018, September 7, 2018, May 16, 2019, October 3, 2019, January 27, 2020, March 31, 2020, June 24, 2020, July 31, 2020, September 17, 2021, October 1, 2021, March 1, 2022, April 22, 2022

HEPATITIS C DIRECT ACTING ANTIVIRALS (DAA)

Prior Authorization required for all Hepatitis C DAA agents:

Preferred Agents: Mavyret and sofosbuvir/velpatasvir (generic Epclusa) are indicated for all genotypes and Vosevi (for patients previously treated with NS5A inhibitors; also indicated for genotype 1a or 3 previously treated with sofosbuvir without an NS5A inhibitor).

If prescribing non-preferred alternatives please provide documentation of medical reason(s) why the patient is unable to take the preferred medication otherwise, all requests for a non-preferred agent will be redirected to a preferred agent(s).

LENGTH OF AUTHORIZATION: 8 weeks, 12 weeks or 16 weeks.

INITIAL REVIEW CRITERIA:

1. Adult patient age ≥ 18 years of age; ≥ 3 years of age and older for Mavyret; or ≥ 3 years of age and older for Epclusa (sofosbuvir/velpatasvir); **AND**
2. Patient has no history of the requested medication (no claims history or reference in medical records to previous trial and failure of requested medication); **AND**
3. Submission of Hepatitis B surface antigen screening to verify no reactivation; **AND**
4. Baseline HCV RNA must be submitted with a collection date within the past six months. **Prescriber must submit lab documentation indicating HCV genotype and quantitative viral load; AND**
5. Patient meets the diagnosis and criteria outlined in Dosing and Administration below; **AND**
6. Patient commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment; **AND**
7. **No early refills will be allowed due to lost, stolen medications or vacation override; AND**
8. Lab results (HCV RNA) are recommended after 4 weeks of therapy and at 12 weeks following completion of therapy. The medication should not be discontinued or interrupted if HCV RNA levels are not available during treatment or are not performed; **AND**
9. Females of childbearing potential must have a negative pregnancy test collected within 30 days prior to the initiation of therapy with ribavirin; **AND**
10. For HIV-1 co-infected patients, patients must have the following:
    - Documented HIV-1 diagnosis, **AND**
    - CD4 count greater than 500 cells/mm^3, if patient is not taking antiretroviral therapy; **OR**
    - CD4 count greater than 200 cells/mm^3, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL).

RETREATMENT REVIEW CRITERIA AFTER FAILURE WITH A DAA AGENT:

1. Member was adherent to previous therapy as evidenced by pharmacy claims; **AND**
2. Submission of Hepatitis B surface antigen screening/test to verify no reactivation; **AND**
3. One of the Following:
    - Evidence of failure to achieve a sustained virologic response (SVR) or lack of efficacy during treatment:
        - Must submit proof showing detectable HCV RNA in the serum, when assessed by a sensitive polymerase chain reaction (PCR) assay, 12 or more weeks after completing treatment; or a 10-fold increase of viral load at week 6 of treatment;

OR

- Evidence of adverse event that required therapy discontinuation:
  - Laboratory results (eg: CBC, LFTs, etc.) and/or clinical presentation, **AND**
  - After proper management, there was no improvement of adverse effect (eg: ribavirin-induced anemia should be managed by temporarily withholding ribavirin and/or treating with erythropoiesis-stimulating agent, if indicated, and not discontinuing other DAA)
  - A MedWatch Voluntary Report must be submitted (copy of the report must be submitted with request); **AND**

4. Patient is receiving substance or alcohol abuse counseling services or seeing an addiction specialist as an adjunct to HCV retreatment and it is documented in the medical records for substance abuse related failure; **AND**
5. Baseline HCV RNA following initial treatment must be submitted with a collection date within the past three months. Prescriber must submit lab documentation indicating HCV genotype and quantitative viral load; **AND**
6. Patient commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment; **AND**
7. Females of childbearing potential must have a negative pregnancy test collected within 30 days prior to the initiation of therapy OR medical records must be submitted documenting pregnancy status for ribavirin therapy; **AND**
8. For HIV-1 co-infected patients, patients must have the following:
   - Documented HIV-1 diagnosis, **AND**
   - CD4 count greater than 500 cells/mm3, if patient is not taking antiretroviral therapy; **OR**
   - CD4 count greater than 200 cells/mm3, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL); **AND**
9. No early refills will be allowed due to lost, stolen medications or vacation override.

DENIAL CRITERIA FOR RETREATMENT:

1) Short life expectancy (less than 12 months) that cannot be remediated by treating HCV infection, by transplantation, or by other directed therapy
2) Member was non-adherent to initial regimen as evidenced by medical record and/or pharmacy claims;

MAVYRET

HCV & HCV/HIV-1 co-infection	Treatment Naïve	Regimen and Duration
Genotypes 1-6	No cirrhosis or compensated cirrhosis (Child-Pugh A)	8 weeks
	Liver or kidney transplant recipients.	12 weeks

MAVYRET

HCV & HCV/HIV-1 co-infection	Treatment experienced	Regimen and Duration	
Genotype 1	Previous regimens with an HCV NS5A inhibitor (e.g. ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin) without prior treatment with a	No cirrhosis	Compensated cirrhosis (Child Pugh-A), or liver or kidney transplant recipients.
		16 weeks	16 weeks

	NS3/4A protease inhibitor (e.g. telaprevir, boceprevir or simeprevir).		
Genotype 1	Previous regimens with an NS3/4A protease inhibitor (e.g. telaprevir, boceprevir or simeprevir) without prior treatment with an NS5A inhibitor.	No cirrhosis	Compensated cirrhosis (Child-Pugh A)
		12 weeks	12 weeks
Genotype 1, 2, 4, 5 or 6	Previous regimens containing pegylated interferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.	No cirrhosis	Compensated cirrhosis (Child-Pugh A), or liver or kidney transplant recipients.
		8 weeks	12 weeks
Genotype 3	Previous regimens containing pegylated interferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.	No cirrhosis	Compensated cirrhosis (Child- Pugh A), or liver or kidney transplant recipients.
		16 weeks	16 weeks

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as:
  - Tablets: 100mg glecaprevir and 40 mg pibrentasvir.
  - Oral pellets: 50mg glecaprevir and 20 mg pibrentasvir.

SOFOSVUVIR/VELPATASVIR

HCV & HCV/HIV-1 co-infection	Treatment Naïve	Regimen and Duration
Genotypes 1-6	*No cirrhosis or compensated cirrhosis (Child-Pugh A). †	12 weeks
Genotypes 1-6	*Decompensated cirrhosis (Child-Pugh B and C).	12 weeks + ribavirin

*no dosage adjustment is recommended in patients with any degree of renal impairment, including dialysis.
†no dosage adjustment is recommended in liver transplant recipients.

SOFOSVUVIR/VELPATASVIR

HCV & HCV/HIV-1 co-infection	Treatment Experienced	Regimen and Duration
Genotypes 1-6	*No cirrhosis or compensated cirrhosis (Child-Pugh A). †	12 weeks
Genotypes 1-6	*Decompensated cirrhosis (Child-Pugh B and C).	12 weeks + ribavirin

*no dosage adjustment is recommended in patients with any degree of renal impairment, including dialysis.
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DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as:
    - Tablets: 400 mg of sofosbuvir and 100 mg of velpatasvir; 200 mg of sofosbuvir and 50 mg of velpatasvir.
    - Oral pellets: 200 mg of sofosbuvir and 50 mg of velpatasvir; 150 mg of sofosbuvir and 37.5 mg of velpatasvir.

VOSEVI

HCV & HCV/HIV-1 co-infection	Treatment Experienced	Regimen and Duration
Genotype 1a or 3	No cirrhosis or compensated cirrhosis (Child Pugh-A) previous regimen with sofosbuvir without an NS5A inhibitor.	12 weeks
Genotype 1-6	No cirrhosis or compensated cirrhosis (Child Pugh-A) previous regimen with an NS5A inhibitor (e.g. daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir).	12 weeks

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 400 mg sofosbuvir, 100 mg velpatasvir, and 100 mg voxilaprevir tablets.