

Policy Type: PA/SP

Pharmacy Coverage Policy: EOCCO036

Description

The listed treatments for Hepatitis C are for orally administered Direct-Acting Antiviral (DAA) therapies.

Length of Authorization

- Initial: 8-16 weeks based on liver status*
- Renewal: none

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit*
glecaprevir/pibrentasvir (Mavyret)	100 mg/40 mg tablet	HCV Genotype 1, 2, 3, 4, 5, 6 Treatment naïve or experienced	84 tablets/28 days
	50mg/20mg oral pellets		140 packets/28 days
sofosbuvir (Sovaldi)	200 mg oral tablet	HCV Genotype 2 or 3 Treatment naïve or experienced	28 tablets/28 days
	400 mg oral tablet	HCV Genotype 1, 2, 3, 4 Treatment naïve or experienced	
ledipasvir/sofosbuvir (Harvoni)	45 mg /200 mg tablet	HCV Genotype 1, 4, 5, 6 Treatment naïve or experienced	28 tablets/28 days
	90 mg /400 mg tablet	HCV Genotype 1, 2, 3, 4, 5, 6 Treatment naïve or experienced	
ledipasvir/sofosbuvir (authorized generic)	45 mg /200 mg tablet	HCV Genotype 1, 4, 5, 6 Treatment naïve or experienced	28 tablets/28 days
	90 mg /400 mg tablet	HCV Genotype 1, 2, 3, 4, 5, 6 Treatment naïve or experienced	
velpatasvir/sofosbuvir (Epclusa)	50 mg / 200 mg tablet	HCV Genotype 1, 2, 3, 4, 5, 6 Treatment naïve or experienced	56 tablets/28 days
	100 mg/ 400 mg tablet		28 tablets/28 days

	150mg/37.5mg oral pellets		28 packets/28 days
	200mg/50mg oral pellets		56 packets/28 days
velpatasvir/sofosbuvir (authorized generic)	100 mg/400 mg tablet	HCV Genotype 1, 2, 3, 4, 5, 6 Treatment naïve or experienced	28 tablets/28 days
daclatasvir (Daklinza)	30 mg, 60 mg, 90 mg tablet	HCV Genotype 1, 3	28 tablets/28 days
elbasvir/grazoprevir (Zepatier)	50 mg /100 mg tablet	HCV Genotype 4	28 tablets/28 days
velpatasvir/sofosbuvir/voxilaprevir (Vosevi)	100 mg/400 mg/100 mg tablet	HCV Genotype 1, 2, 3, 4, 5, 6 Treatment experienced	28 tablets/28 days
simeprevir (Olysio)	150 mg capsule	HCV Genotype 1 Treatment naïve or experienced	28 capsules/28 days
ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira Pak)	12.5/75/50 mg oral tablet and dasabuvir 250 mg tablet	HCV Genotype 1a, 1b Treatment naïve or experienced	1 box/ 28 days
ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira XR)	12.5/75/50 mg oral tablet and dasabuvir 250 mg tablet	HCV Genotype 1a, 1b Treatment naïve or experienced	1 box/28 days
ombitasvir/paritaprevir/ritonavir (Technivie)	12.5/75/50 mg tablet	HCV Genotype 4	1 box/28 days

*See Oregon Health Authority's Hepatitis C Direct-Acting Antivirals criteria for specific treatment durations

Initial Evaluation

- i. For criteria, please reference Oregon Health Authority's Hepatitis C Direct-Acting Antivirals at: <http://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx> (The criteria is stored about halfway down the webpage).

References

1. Olysio [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals; November 2013.
2. Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; December 2013.
3. Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; October 2014.

4. Viekira Pak [Prescribing Information]. North Chicago, IL: Abbvie Inc.; December 2014.
5. Technivie [Prescribing Information]. North Chicago, IL: Abbvie Inc.; July 2015
6. Daklinza [Prescribing Information]. Princeton, NJ: Bristol Myers Squibb; July 2015.
7. Zepatier [Prescribing Information]. Whitehouse Station, NJ; March 2016.
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9. Mavyret [Prescribing Information]. North Chicago, IL: AbbVie. August 2017.
10. Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; July 2017.
11. Boursier J, de Ledinghen V, Zarski JP, Fouchard-Hubert I Gallois Y, Oberti F, et al: Comparison of Eight Diagnostic Algorithms for Liver Fibrosis in Hepatitis C: New Algorithms Are More Precise and Entirely Noninvasive. *Hepatology* 2012; 55(1): 58-67.
12. 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>.
13. Center for Disease Control Website <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section1>. Accessed 8/1/15.
14. Center for Disease Control Website <http://www.cdc.gov/knowmorehepatitis/timeline.htm>. Accessed 8/17/16
15. 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 28, 2016.

Policy Implementation/Update:

Action and Summary of Changes	Date
Added Mavyret and Eplclusa oral pellets to the QL table	11/2021
Criteria converted to policy format	10/2019
Updated to add New FDA approved agents, Mavyret and Vosevi	01/2018
Updated to reflect MOU executed mandate	05/2017
Updated with new OHA criteria	01/2017
Updated with new CCO requirements	11/2016
Updated statements to indication SVR12 will be requested	08/2016
Align with OHA criteria	07/2016
Previous reviews	06/2016, 04/2016, 11/2015
Policy created	05/2015