EXPRESS SCRIPTS®

# PREFERRED SPECIALTY MANAGEMENT (PSM) POLICY

**POLICY:** Hepatitis C Virus (HCV) Direct-Acting Antivirals (DAAs)

**TAC REVIEW DATE:** 09/27/2017

**LAY CRITERIA EFFECTIVE DATE:** See individual drugs for effective dates.

**DRUGS AFFECTED:**

- Daklinza™ (daclatasvir tablets – Bristol Meyers Squibb)
- Epclusa® (velpatasvir/sofosbuvir – Gilead)
- Harvoni® (ledipasvir/sofosbuvir tablets – Gilead)
- Mavyret™ (glecaprevir/pibrentasvir – AbbVie)
- Olysio® (simeprevir tablets – Janssen)
- Sovaldi® (sofosbuvir tablets – Gilead)
- Technivie ™ (co-formulated ombitasvir, paritaprevir, and ritonavir tablets – AbbVie)
- Viekira Pak™ (ombitasvir/paritaprevir/ritonavir tablets; dasabuvir tablets, co-packaged – AbbVie)
- Viekira XR™ (dasabuvir/ombitasvir/paritaprevir/ritonavir extended-release tablets – AbbVie)
- Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir tablets – Gilead)
- Zepatier™ (grazoprevir/elbasvir tablets – Merck)

**OVERVIEW**

Daklinza is indicated in combination with Sovaldi for the treatment of adults with genotypes 1 and 3 chronic hepatitis C virus (HCV).[2,7] Epclusa is indicated for the treatment of chronic HCV in adults with genotypes 1 through 6.[8] Harvoni is indicated for the treatment of adults and pediatric patients ≥ 12 years of age or weighing ≥ 35 kg with genotypes 1, 4, 5, and 6 chronic HCV.[1] Mavyret is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).[22] Mavyret is also indicated for the treatment of adult patients with HCV genotype 1 infection who have previously been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both. Sovaldi is indicated for the treatment of adults with genotypes 1, 2, 3, and 4 chronic HCV in combination with ribavirin or pegylated interferon + ribavirin (PR).[2] Sovaldi is also indicated in pediatric patients ≥ 12 years of age or weighing ≥ 35 kg with genotypes 2 or 3 chronic HCV in combination with ribavirin. Olysio is indicated for the treatment of genotype 1 and genotype 4 chronic HCV in combination with PR; in genotype 1 chronic HCV, Olysio is also indicated in combination with Sovaldi.[3] Viekira Pak/Viekira XR are indicated for the treatment of adults with genotype 1 chronic HCV.[4,17] Technivie is indicated for the treatment of adults with genotype 4 chronic HCV.[5] Vosevi is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A): Who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor; and for patients with genotype 1a or 3 infection and who have previously been treated with an HCV regimen containing Sovaldi without an NS5A inhibitor.[21] Zepatier is indicated for the treatment of adults with genotypes 1 and 4 chronic HCV.[6] Daklinza, Epclusa, and Harvoni are also

indicated in individuals with decompensated liver disease in combination with ribavirin. Daklinza and Harvoni (in adults) are indicated in post-transplant recurrent HCV (see respective prescribing information for details); Viekira Pak is indicated in patients with recurrent HCV post-liver transplant who do *not* have cirrhosis.

The standard of care for all genotypes is all-oral therapy. For more information on criteria for Daklinza, Epclusa, Harvoni, Mavyret, Viekira Pak/Viekira XR, Olysio, Sovaldi, Technivie, Vosevi, or Zepatier within a Prior Authorization (PA) program by specific condition refer to the respective *PA policy*.[9-16,18-20] For additional information on guidelines and clinical data see the *Hepatitis C Virus Direct Acting Antivirals Therapy Class Summary*.

**POLICY STATEMENT**

This PSM program requires the patient to meet *ESI Standard Prior Authorization (PA)* criteria for the requested drug and requires the patient to try the preferred product, when clinically appropriate, prior to the approval of the non-preferred products. The specific requirements of the program depend upon the clinical situation and the medication requested.

For patients with **genotype 1 chronic HCV**, the preferred products are Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, and Vosevi. Patients with genotype 1 requesting Daklinza, Olysio, Sovaldi, or Zepatier will be directed to first try one of Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi. For **genotype 2 chronic HCV,** the preferred products are Epclusa, Mavyret, and Vosevi. For **genotype 3 chronic HCV,** the preferred products are Epclusa, Mavyret, and Vosevi. Patients with genotype 3 requesting Daklinza and/or Sovaldi will be directed to first try one of Epclusa, Mavyret, or Vosevi. For **genotype 4 chronic HCV,** the preferred products are Epclusa, Harvoni, Mavyret, Technivie, and Vosevi. Patients with genotype 4 requesting Zepatier will be directed to first try one of Epclusa, Harvoni, Mavyret, Technivie, or Vosevi. For **genotype 5 or 6 chronic HCV,** the preferred products are Epclusa, Harvoni, Mavyret, and Vosevi.

**Documentation: Documentation will be required for patients requesting a non-preferred product where noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or laboratory data.**

All approvals for preferred and non-preferred products are provided for the duration documented in the respective *ESI Standard PA policy*.

**Automation:** None

**Preferred Products for Genotype 1 (chronic HCV only):** Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, Vosevi
**Non-Preferred Products for Genotype 1(chronic HCV only):** Daklinza, Olysio, Sovaldi, Zepatier

**Preferred Products for Genotype 2 (chronic HCV only):** Epclusa, Mavyret, Vosevi

**Preferred Products for Genotype 3 (chronic HCV only):** Epclusa, Mavyret, Vosevi
**Non-Preferred Products for Genotype 3 (chronic HCV only):** Daklinza, Sovaldi

**Preferred Products for Genotype 4 (chronic HCV only):** Epclusa, Harvoni, Mavyret, Technivie, Vosevi
**Non-Preferred Products for Genotype 4 (chronic HCV only):** Zepatier

**Preferred Products for Genotype 5 or 6 (chronic HCV only):** Epclusa, Harvoni, Mavyret, Vosevi

## RECOMMENDED EXCEPTION CRITERIA

| Trade Name | Exception |
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| Daklinza<br><br>**Lay criteria effective date:**<br>*In Progress* | **1. Genotype 1 Recurrent HCV Post-Liver Transplantation:** If the patient is NOT currently receiving Daklinza, approve Daklinza for the duration specified in the *ESI Daklinza Standard PA policy* if the patient has met the *ESI Daklinza PA policy* criteria.<br>**2. Genotype 1 Chronic HCV:** If the patient is NOT currently receiving Daklinza, approve Daklinza for the duration specified in the *ESI Standard Daklinza PA policy* if the patient meets all of the following criteria (A, B, and C):<br>**A)** The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See *Criteria 3*); AND<br>**B)** The patient has met *ESI Standard Daklinza PA policy* criteria; AND<br>**C)** The patient has completed a course of therapy with ONE of Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi **[documentation required]**; OR<br>**3. Genotype 1 Chronic HCV, Compensated or Decompensated Cirrhosis:** If the patient is NOT currently receiving Daklinza, approve Daklinza for the duration specified in the *ESI Standard Daklinza PA policy* if the patient meets both of the following criteria (A, B, and C):<br>**A)** The patient has compensated cirrhosis (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis. **[documentation required]**; AND<br>**B)** The patient has met the *ESI Standard Daklinza PA policy*; AND<br>**C)** The patient has completed a course of therapy with ONE of Epclusa or Harvoni and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa or Harvoni **[documentation required]**; OR<br>**4. Genotype 3 Chronic HCV:** If the patient is NOT currently receiving Daklinza, approve Daklinza for the duration specified in the *ESI Standard Daklinza PA policy* if the patient has met the *ESI Standard Daklinza PA policy* if the patient meets the following criteria (A, B, and C):<br>**A)** The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See *Criteria 5*); AND<br>**B)** The patient has met the *ESI Standard Daklinza PA policy*; AND<br>**C)** The patient has tried ONE of Epclusa, Mavyret, or Vosevi and has documentation that he/she did not achieve a sustained viral response |

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| | (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa, Mavyret, or Vosevi [**documentation required];** OR<br>**5. Genotype 3 Chronic HCV, Compensated or Decompensated Cirrhosis:** If the patient is NOT currently receiving Daklinza, approve Daklinza for the duration specified in the *ESI Standard Daklinza PA policy* if the patient meets both of the following criteria (A, B, and C):<br>**A)** The patient has compensated cirrhosis (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis. **[documentation required]**; AND<br>**B)** The patient has met the *ESI Standard Daklinza PA policy*; AND<br>**C)** The patient has completed a course of therapy with Epclusa has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa **[documentation required]**; OR<br>**6. Genotype 3 Recurrent HCV Post-Liver Transplantation:** If the patient is NOT currently receiving Daklinza, approve Daklinza for the duration specified in the *ESI Standard Daklinza PA policy* if the patient has met the *ESI Daklinza PA policy* criteria.<br>**7.** For patients who meet criteria 2A and 2B but NOT 2C, Daklinza is not approved; offer to review for Epclusa, Harvoni, Viekira Pak/Viekira XR using the *ESI Standard Epclusa, Harvoni, Mavyret, Viekira, or Vosevi PA policy,* respectively.<br>**8.** For patients who meet criteria 3A and 3B but NOT 3C, Daklinza is not approved; offer to review for Epclusa or Harvoni using the *ESI Standard Epclusa or Harvoni PA policy, respectively*.<br>**9.** For patients who meet criteria 4A and 4B but NOT 4C, Daklinza is not approved; offer to review for Epclusa, Mavyret, or Vosevi using the *ESI Standard Epclusa, Mavyret, or Vosevi PA policy,* respectively.<br>**10.** For patients who meet criteria 5A and 5B, but NOT 5C, Daklinza is not approved; offer to review for Epclusa using the *ESI Standard Epclusa PA policy*.<br>**11.** If the patient is continuing therapy with Daklinza, refer to the *ESI Standard Daklinza PA policy.* |
| Epclusa<br><br>**Effective Date:** *In Progress* | **1. Genotype 1, 2, 3, 4, 5, or 6 Chronic HCV:** If the patient is NOT currently receiving Epclusa, approve Epclusa for the duration specified in the *ESI Standard Epclusa PA policy* if the patient has met the *ESI Standard Epclusa PA policy.*<br>**2.** If the patient is continuing therapy with Epclusa refer to the *ESI Standard Epclusa PA policy.* |
| Harvoni<br><br>**Lay criteria effective date:** *Previously in Effect* | **1. Genotype 1 Recurrent or Genotype 4 Recurrent HCV Post-Liver Transplantation:** If the patient is NOT currently receiving Harvoni, approve Harvoni for the duration specified in the *ESI Standard Harvoni PA policy* if the patient has met the *ESI Standard Harvoni PA policy* criteria.<br>**2. Genotype 1 Chronic HCV:** If the patient is NOT currently receiving Harvoni, approve Harvoni for the duration specified in the *ESI Standard Harvoni PA policy* if the patient has met the *ESI Standard Harvoni PA policy*.<br>**3. Genotype 4, 5, or 6 Chronic HCV**: If the patient is NOT currently receiving Harvoni, approve Harvoni for the duration specified in the *ESI Standard* |

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| | *Harvoni PA policy* if the patient has met the *ESI Standard Harvoni PA policy* criteria.<br>**4.** If the patient is continuing therapy with Harvoni, refer to the *ESI Standard Harvoni PA policy*. |
| Sovaldi<br><br>**Lay criteria effective date:**<br>*In Progress* | **1. Genotype 1, 2, or 3 Recurrent HCV Post-Liver Transplant:** If the patient is NOT currently receiving Sovaldi, approve Sovaldi for the duration specified in the *ESI Standard Sovaldi PA policy* criteria.<br>**2. Genotype 1 Chronic HCV, Adults (≥ 18 years of age):** If the patient is NOT currently receiving Sovaldi, approve Sovaldi for the duration specified in the *ESI Standard Sovaldi PA policy* if the patient meets all of the following criteria (A, B, and C):<br>**A.** The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See *Criteria 3*); AND<br>**B.** Patient has met *ESI Standard Sovaldi PA policy* criteria; AND<br>**C.** The patient has completed a course of therapy with ONE of Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi **[documentation required]**; OR<br>**3. Genotype 1 Chronic HCV Compensated or Decompensated Cirrhosis, Adults (≥ 18 years of age):** If the patient is NOT currently receiving Sovaldi, approve Sovaldi for the duration specified in the *ESI Standard Sovaldi PA policy* if the patient meets both of the following criteria (A, B, and C):<br>**A.** The patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis **[documentation required]**; AND<br>**B.** The patient has met the *ESI Standard Sovaldi PA policy*; AND<br>**C.** The patient has completed a course of therapy with ONE of Epclusa or Harvoni and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa or Harvoni **[documentation required]**.<br>**4. Genotype 2 Chronic HCV, Pediatric Patients (age ≥ 12 years or ≥ 35 kg):** If the patient is NOT currently receiving Sovaldi, approve Sovaldi for the duration specified in the *ESI Standard Sovaldi PA policy* if the patient has met the *ESI Standard Sovaldi PA olicy* Criteria.<br>**5. Genotype 3 Chronic HCV, Pediatric Patients (age ≥ 12 years or ≥ 35 kg):** If the patient is NOT currently receiving Sovaldi, approve Sovaldi for the duration specified in the *ESI Standard Sovaldi PA policy* if the patient has met the *ESI Standard Sovaldi PA policy* Criteria.<br>**6. Genotype 3 Chronic HCV, Adults (≥ 18 years of age):** If the patient is NOT currently receiving Sovaldi, approve Sovaldi for the duration specified in the *ESI Standard Sovaldi PA policy* if the patient meets all of the following criteria (A, B, and C):<br>**A.** The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See *Criteria 7*); AND<br>**B.** Patient has met *ESI Standard Sovaldi PA policy* criteria; AND<br>**C.** The patient has completed a course of therapy with ONE of Epclusa, |

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| | Mavyret, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa, Mavyret, or Vosevi **[documentation required]**; OR<br>**7. Genotype 3 Chronic HCV Compensated or Decompensated Cirrhosis, Adults (≥ 18 years of age):** If the patient is NOT currently receiving Sovaldi, approve Sovaldi for the duration specified in the *ESI Standard Sovaldi PA policy* if the patient meets both of the following criteria (A, B, and C):<br>**A.** The patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis **[documentation required]**; AND<br>**B.** The patient has met the *ESI Standard Sovaldi PA policy*; AND<br>**8.** The patient has completed a course of therapy with Epclusa and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa **[documentation required]**.For patients who meet criteria 2A and 2B (*ESI Standard Sovaldi PA policy*) but do NOT meet criteria 2C above Sovaldi is not approved, offer to review for Harvoni, Viekira Pak, or Viekira XR using the *ESI Standard Harvoni or Viekira PA policy*, respectively.<br>**9.** For patients who meet criteria 3A and 3B but do not meet criteria 3C above Sovaldi is not approved. Offer to review for Harvoni using the *ESI Standard Harvoni PA policy*.<br>**10.** For patients who meet criteria 6A and 6B but do NOT meet 6C above Sovaldi is not approved, offer to review for Epclusa, Mavyret, or Vosevi using the *ESI Standard Epclusa, Mavyret, or Vosevi PA policy*, respectively.<br>**11.** For patients who meet criteria 7A or 7B, but do NOT meet 7C above Sovaldi is not approved, offer to review for Epclusa using the *ESI Standard Epclusa PA policy*.<br>**12.** If the patient is continuing therapy with Sovaldi, refer to the *ESI Standard Sovaldi PA policy.* |
| Mavyret<br><br>**Lay criteria effective date:** *In Progress* | **1. Genotype 1, 2, 3, 4, 5, or 6 chronic HCV:** If the patient is NOT currently receiving Mavyret, approve Mavyret for the duration specified in the *ESI Standard Mavyret PA policy* criteria.<br>**2.** If the patient is continuing therapy with Mavyret, refer to the *ESI Standard Mavyret PA policy*. |
| Olysio<br><br>**Lay criteria effective date:** *In Progress* | **3. Genotype 1 Recurrent HCV post liver transplantation:** If the patient is NOT currently receiving Olysio, approve Olysio for the duration specified in the *ESI Standard Olysio PA policy* criteria.<br>**4. Genotype 1 Chronic HCV:** If the patient is NOT currently receiving Olysio, approve Olysio for the duration specified in the *ESI Standard Olysio PA policy* if the patient meets both of the following criteria (A and B):<br>**A.** Patient has met *ESI Standard Olysio PA policy* criteria; AND<br>**B.** The patient has completed a course of therapy with ONE of Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi **[documentation required]**; OR |

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| | **5.** For patients who meet criteria 2A (*ESI Standard Olysio PA policy*) but do not meet criteria 2B above, Olysio is not approved, offer to review for Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi using the *ESI Standard Epclusa, Harvoni, Mavyret, Viekira, or Vosevi PA policy*.<br>**6.** If the patient is continuing therapy with Olysio, refer to the *ESI Standard Olysio PA policy*. |
| Technivie<br><br>**Lay Criteria Effective Date:** *In Progress* | **1. Genotype 4 Chronic HCV:** If the patient is NOT currently receiving Technivie, approve Technivie for the duration specified in the *ESI Standard Technivie PA policy*. If the patient is continuing therapy with Technivie, refer to the *ESI Standard Technivie PA policy*. |
| Viekira Pak/Viekira XR<br><br>**Lay Criteria Effective Date:** *Previously in Effect* | **1. Genotype 1 Chronic HCV:** If the patient is NOT currently receiving Viekira Pak/Viekira XR, approve Viekira Pak or Viekira XR for the duration specified in the *ESI Standard Viekira PA policy*.<br>**2. Genotype 1 Recurrent HCV Post-Liver Transplantation:** If the patient is NOT currently receiving Viekira Pak/Viekira XR, approve Viekira Pak or Viekira XR for the duration specified in the *ESI Standard Viekira PA policy*.<br>**3.** If the patient is continuing therapy with Viekira Pak or Viekira XR, refer to the *ESI Standard Viekira PA policy*. |
| Vosevi<br><br>**Lay Criteria Effective Date:** *In Progress* | **1. Genotype 1, 2, 3, 4, 5, or 6 chronic HCV.** If the patient is NOT currently receiving Vosevi, approve Vosevi for the duration specified in the *ESI Standard Vosevi PA policy*.<br>**2.** If the patient is continuing therapy with Vosevi, refer to the *ESI Standard Vosevi* PA policy. |
| Zepatier<br><br>**Lay criteria effective date:** *In Progress* | **1. Genotype 1 or 4 with Renal Impairment (estimated creatinine clearance < 30 mL/min):** If the patient is NOT currently receiving Zepatier, approve Zepatier for the duration specified in the *ESI Standard Zepatier PA policy* if the patient meets all of the following criteria (A and B):<br>**A.** The patient has met *ESI Standard Zepatier PA policy* criteria; AND<br>**B.** The patient has completed a course of therapy with Mavyret and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Mavyret **[documentation required]**.<br>**2. Genotype 1 Chronic HCV:** If the patient is NOT currently receiving Zepatier, approve Zepatier for the duration specified in the *ESI Standard Zepatier PA policy* if the patient meets all of the following criteria (A and B):<br>**A.** The patient has met *ESI Standard Zepatier PA policy* criteria; AND<br>**B.** The patient has completed a course of therapy with ONE of Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi **[documentation required].** OR<br>**3. Genotype 4 Chronic HCV:** If the patient is NOT currently receiving Zepatier, approve Zepatier for the duration specified in the *ESI Standard Zepatier PA policy* if the patient meets the all of the following criteria (A and B): |

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| | **A)** The patient has met *ESI Standard Zepatier PA policy* criteria; AND<br>**B)** The patient has completed a course of therapy with ONE of Epclusa, Harvoni, Mavyret, Technivie, or Vosevi and has documentation that he/she did not achieve sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with Epclusa, Harvoni, Mavyret, Technivie, or Vosevi **[documentation required].** OR<br>**4.** For patients who meet criteria 2A but not 2B, Zepatier is not approved; offer to review for Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, or Vosevi using the *ESI Standard Epclusa, Harvoni, Mavyret, Viekira, or Vosevi PA policy*, respectively.<br>**5.** For patients who meet criteria 3A but not 3B, Zepatier is not approved; offer to review for Epclusa, Harvoni, Mavyret, Technivie, or Vosevi using the *ESI Standard Epclusa, Harvoni, Mavyret, Technivie, or Vosevi PA policy*, respectively.<br>**6.** If the patient is continuing therapy with Zepatier, refer to the *ESI Standard Zepatier PA policy.* |

**REFERENCES**

1. Harvoni® tablets [prescribing information]. Foster City, CA: Gilead; April 2017.
2. Sovaldi® tablets [prescribing information]. Foster City, CA: Gilead; April 2017.
3. Olysio® capsules [prescribing information]. Titusville, NJ: Janssen; May 2016.
4. Viekira Pak ™ tablets [prescribing information]. North Chicago, IL: AbbVie, Inc.; April 2016.
5. Technivie™ tablets [prescribing information]. North Chicago, IL: AbbVie, Inc.; June 2016.
6. Zepatier™ tablets [prescribing information]. Whitehouse Station, NJ: Merck; January 2016.
7. Daklinza™ tablets [prescribing information]. Princeton, NJ: Bristol-Meyers Squibb; April 2016.
8. Epclusa tablets [prescribing information]. Foster City, CA: Gilead; February 2017.
9. Harvoni prior authorization policy. Express Scripts, Inc. Updated: 09/21/2016; Selected revision 04/12/2017.
10. Sovaldi prior authorization policy. Express Scripts, Inc. Updated: 02/15/2017; Selected revision 04/12/2017.
11. Olysio prior authorization policy. Express Scripts, Inc. Updated: 09/13/2017.
12. Technivie prior authorization policy. Express Scripts, Inc. Updated: 08/17/2016; Selected revision 03/08/2017.
13. Viekira prior authorization policy. Express Scripts, Inc. Updated: 09/13/2017.
14. Technivie prior authorization policy. Express Scripts, Inc. Updated: 08/17/2016; Selected revision 03/08/2017.
15. Zepatier prior authorization policy. Express Scripts, Inc. Updated: 02/15/2017.
16. Epclusa prior authorization policy. Express Scripts, Inc. Updated: 06/14/2017.
17. Viekira XR™ tablets [prescribing information]. North Chicago, IL: AbbVie, Inc.; July 2016.
18. Daklinza prior authorization policy. Express Scripts, Inc. Updated: 08/23/2017.
19. Mavyret prior authorization policy. Express Scripts, Inc. 08/04/2017
20 Vosevi prior authorization policy. Express Scripts, Inc. 07/26/2017.
21. Vosevi™ tablets [prescribing information]. Foster City, CA: Gilead; July 2017.
22. Mavyret™ tablets [prescribing information]. North Chicago, IL: AbbVie; August 2017.

**HISTORY**

| Type of Revision | Summary of Changes* | TAC Approval Date | Lay Criteria Effective Date |
|---|---|---|---|
| New policy | -- | 01/01/2017 | 01/01/2017 |
| Harvoni PA Policy | Added approval criteria for patients ≥ 12 years of age or ≥ 35 kg with genotype 1, 4, 5, or 6 chronic HCV.<br><br>Modified exclusion for patients < 18 years of age to agree with updated age indication for Harvoni. | 04/12/2017 | 05/08/2017 |

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| Sovaldi PA Policy | Added approval criteria for patients ≥ 12 years of age or ≥ 35 kg with genotype 2 or 3 chronic HCV.<br><br>Modified exclusion for patients < 18 years of age to agree with updated age indication for Harvoni. | 04/12/2017 | 05/09/2017 |
| DAA PSM Policy – Sovaldi | Added indications for genotype 2 and 3 chronic HCV for pediatric patients. | 04/12/2017 | 05/08/2017 |
| DAA PSM Policy – Harvoni | No changes to clinical policy; lay criteria updated with new PA. | 04/12/2017 | 05/08/2017 |
| DAA PSM Policy - Epclusa | Notes added to address new PA indication in patients previously treated with Epclusa. | 06/14/2017 | 07/05/2017 |
| Epclusa PA Policy | Criteria for patients with genotype 1, 2, or 3 chronic HCV with prior null response, prior partial response, or relapse to Epclusa with cirrhosis or advanced cirrhosis added as an approvable condition.<br><br>The condition not recommended for approval of retreatment with Epclusa in patients who were prior null or partial responders or relapsers was removed. This in now addressed in separate criteria. | 06/14/2017 | 07/07/2017 |
| Viekira PA Policy | No criteria changes | 09/13/2017 | Previously in Effect |
| Olysio PA Policy | No criteria changes | 09/13/2017 | Previously in Effect |
| Harvoni PA Policy | No criteria changes | 09/20/2017 | Previously in Effect |
| DAA PSM Policy – Daklinza | Criteria for genotype 1 chronic HCV were modified to add Epclusa, Mavyret, and Vosevi to the list of one therapy that must be tried prior to Daklinza. Epclusa, Mavyret, and Vosevi are all preferred for genotype 1.<br><br>Criteria for genotype 1 chronic HCV with compensated or decompensated cirrhosis were modified to add Epclusa to the list of one therapy that must be tried prior to Daklinza. Epclusa is indicated for both compensated and decompensated cirrhosis; Mavyret and Vosevi are not recommended in decompensated cirrhosis.<br><br>For patients with genotype 3 chronic HCV with compensated or decompensated cirrhosis, documentation is required for the presence of compensated or decompensated cirrhosis and failure to attain SVR12 of Epclusa is required (documentation required). | 09/20/2017 | In Progress |
| DAA PSM – Epclusa | Epclusa was added to a preferred product for genotype 1 HCV. Criteria requiring a trial of a preferred product for genotype 1 were removed. | 09/20/2017 | In Progress |
| DAA PSM – Harvoni | No criteria changes | 09/20/2017 | Previously in effect. |
| DAA PSM – Sovaldi | Criteria for genotype 1 chronic HCV (adults ≥ 18 years) were modified to add Epclusa, Mavyret, and Vosevi to the list of one therapy that must be tried prior to Sovaldi. Epclusa, Mavyret, and Vosevi are all preferred for genotype 1.<br><br>For patients with genotype 1 chronic HCV with compensated or decompensated cirrhosis (adults ≥ 18 years), failure to attain SVR12 of Epclusa was added (documentation required) to the criteria (previously only Harvoni was listed).<br><br>For patients with genotype 3 chronic HCV with compensated or | 09/20/2017 | In Progress |

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| | decompensated cirrhosis, documentation is required for the presence of compensated or decompensated cirrhosis and failure to attain SVR12 of Epclusa is required (documentation required). | | |
| DAA PSM – Mavyret | New criteria were created. Mavyret it a preferred product for all genotypes. | 09/20/2017 | In Progress |
| DAA PSM – Olysio | Criteria for genotype 1 chronic HCV (adults ≥ 18 years) were modified to add Epclusa, Mavyret, and Vosevi to the list of one therapy that must be tried prior to Olysio. Epclusa, Mavyret, and Vosevi are all preferred for genotype 1. | 09/20/2017 | In Progress |
| DAA PSM – Technivie | Criteria for genotype 4 chronic HCV were created. Previously, Technivie was a preferred product. Criteria require patients have completed a course of therapy with one of Epclusa, Harvoni, Mavyret, or Vosevi and not attained SVR prior to approval of Technivie [documentation required]. | 09/20/2017 | Never in Effect |
| DAA PSM – Viekira Pak/Viekira XR | No criteria changes | 09/20/2017 | Previously in effect |
| DAA PSM – Vosevi | New criteria were created. Vosevi it a preferred product for all genotypes. | 09/20/2017 | In Progress |
| DAA PSM – Zepatier | Criteria for patients with renal impairment were modified to include genotype 4 (previously only addressed genotype 1). Criteria were modified to add a required trial of Mavyret before Zepatier, documentation of failure to attain SVR after a course of Mavyret is required.<br><br>Criteria for genotype 1 chronic HCV were modified to add Epclusa, Mavyret, and Vosevi to the list of one therapy that must be tried prior to Daklinza. Epclusa, Mavyret, and Vosevi are all preferred for genotype 1.<br><br>Criteria for genotype 4 chronic HCV were modified to add the requirement that the patient has not attained SVR12 with Epclusa, Harvoni, Mavyret, or Vosevi. Previously, Zepatier was not targeted for genotype 4. | 09/20/2017 | Never in Effect |
| DAA PSM – Technivie | Criteria for a trial of a preferred product were removed. Technivie is a preferred product. | 09/27/2017 | In Progress |
| DAA PSM – Zepatier | Criteria for genotype 4 chronic HCV were amended to add Technivie to the list of DAAs a patient must try one of prior to approval of Zepatier. | 09/27/2017 | In Progress |