Clinical Policy: Direct Acting Antiviral (DAA) Medications for Treatment of Hepatitis C Virus (HCV)

Reference Number: AZ.CP.PHAR.44
Effective Date: 01.01.18
Last Review Date: 11.21
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by The Arizona Health Care Cost Containment System (AHCCCS) clinical policy for the treatment of chronic Hepatitis C (HCV): AHCCCS Medical Policy Manual 320-N.

AHCCCS preferred drugs in this class include Mavyret (brand only) and sofosbuvir/velpatasvir (authorized generic of Epclusa).

AHCCCS non-preferred drugs in this class include Brand Epclusa, Brand Harvoni, ledipasvir-sofosbuvir (authorized generic of Harvoni), Sovaldi, Viekira Pak, Vosevi, and Zepatier.

Glecaprevir and pibrentasvir (Mavyret™) are a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor.

Sofosbuvir/velpatasvir (Epclusa®) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor.

Sofosbuvir/ledipasvir (Harvoni®) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor.

Sofosbuvir (Sovaldi®) is hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor.

Dasabuvir/paritaprevir/ritonavir/ombitasvir (Viekira Pak®) is a combination of ombitasvir, a hepatitis C virus (HCV) NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor.

Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) is a fixed-dose combination oral tablet. Sofosbuvir is a nucleotide analog hepatitis C virus (HCV) NS5B polymerase inhibitor, velpatasvir is an NS5A inhibitor, and voxilaprevir is an NS3/4A protease inhibitor.

Grazoprevir/elbasvir (Zepatier®) is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor.

FDA Approved Indication(s)

CLINICAL POLICY
Direct Acting Antiviral (DAA) medications for treatment of Hepatitis C Virus (HCV)

Mavyret is indicated for the treatment of:
- Adult and pediatric patients 3 years and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A)
- Adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor* or an NS3/4A protease inhibitor**, but not both

* In clinical trials, prior NS5A inhibitor experience included ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
** In clinical trials, prior NS3/4A protease inhibitor experience included regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.

Epclusa is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection:
- without cirrhosis or with compensated cirrhosis
- with decompensated cirrhosis for use in combination with ribavirin

Harvoni is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV:
- Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin
- Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin

Sovaldi is indicated for the treatment of chronic HCV infection in:
- Adult patients without cirrhosis or with compensated cirrhosis:
  - Genotype 1 or 4 for use in combination with pegylated interferon and ribavirin (RBV)
  - Genotype 2 or 3 for use in combination with RBV
- Pediatric patients 3 years of age and older with genotype 2 or 3 without cirrhosis or with compensated cirrhosis in combination with RBV

Viekira Pak is indicated for the treatment of adult patients with chronic HCV:
- Genotype 1b without cirrhosis or with compensated cirrhosis
- Genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin (RBV)

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*;
- Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor**.

- Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

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* In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.
** In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir).

Zepatier is indicated for treatment of chronic HCV genotype 1 or 4 infection in adults. Zepatier is indicated for use with ribavirin in certain patient populations.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

Required Documentation for Submission of HCV Prior Authorization Requests:
1. HCV treatment history and responses;
2. Evidence of Hepatitis A and B vaccination or laboratory evidence of immunity;
3. Current medication list;
4. Laboratory results for all of the following:
   a. HCV screen;
   b. Genotype and current baseline viral load;
   c. Total bilirubin;
   d. Albumin;
   e. INR;
   f. CrCl or GFR;
   g. LFTs;
   h. CBC.

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that Epclusa, Epclusa AG, Harvoni, Harvoni AG, Mavyret, Sovaldi, Viekira Pak, Vosevi, Zepatier are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Hepatitis C Infection (must meet all)**:**

1. Diagnosis of chronic HCV infection confirmed by detectable serum HCV RNA by quantitative assay in the last 90 days prior to the date of submission of the request that includes the HCV genotype, viral resistance status (when applicable), hepatic status (Child Pugh Score) and HCV viral load;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;

3. Age of the member is Food and Drug Administration (FDA) approved for the specific HCV DAA product;
4. Member must use **Mavyret** or **Authorized Generic version of Epclusa**, unless contraindicated or clinically significant adverse effects are experienced to both;
5. If request is for Mavyret, Viekira Pak, Vosevi, or Zepatier, and cirrhosis is present, confirmation of Child-Pugh A status;
6. The prescribing provider assesses the member's ability to adhere to the HCV DAA treatment plan and documents this assessment within the clinical record. For members that would benefit from adherence aids, the treating provider shall refer the member to a treatment adherence program;
7. Member agrees to adhere to the proposed course of treatment, including taking medications as prescribed, attending follow-up appointments, and, if applicable, participating in a treatment adherence program;
8. Member has been screened for Hepatitis A and B and shall have received at least one Hepatitis A and at least one Hepatitis B vaccine prior to requesting treatment unless the member demonstrates laboratory evidence of immunity;
9. Prescribed regimen and dose are consistent with an FDA or AASLD-IDSA treatment guidelines for chronic hepatitis C infection;
10. Member has none of limitations from Section III. Diagnoses/Indications for which coverage is NOT authorized.

Approval duration:
Mavyret: 8 to a total of 16 weeks* based on genotype, prior treatment history, and cirrhosis status
Sofosbuvir/velpatasvir (Epclusa AG)/ Sofosbuvir/ledipasvir (Harvoni AG)/Sovaldi/Vosevi: up to a total of 24 weeks* based on genotype, prior treatment history, and cirrhosis status
Viekira Pak: 12 weeks* based on genotype, prior treatment history, and cirrhosis status
Zepatier: up to a total of 16 weeks* based on genotype, prior treatment history, and cirrhosis status *(*Approved duration should be consistent with FDA or AASLD/IDSA treatment guidelines for chronic hepatitis C infection)*

B. Hepatitis C Retreatment Requirements (must meet all)**:**
For members who have HCV and a history of treatment with a Direct Acting Antiviral (DAA), the following criteria shall be met for DAA retreatment approval:

1. The member was adherent to previous DAA therapy as evidenced by medical records and/or pharmacy prescription claims. If prior therapy was discontinued due to adverse effects from the DAA, the medical record shall be provided which documents these adverse effects and recommendation of discontinuation by treatment provider;
2. The member's ability to adhere to the planned course of retreatment has been assessed by the treating provider and documented within the clinical record;

3. Resistance-associated polymorphism testing, when applicable, has been completed and submitted with the prior authorization request when:
   a. Required for regimens whereby the FDA requires such testing prior to treatment to ensure clinical appropriateness, and
   b. Deemed medically necessary by the clinical reviewer prior to approval of the requested regimen;
4. Member has none of limitations from Section III. Diagnoses/Indications for which coverage is NOT authorized;

Approval duration:
Mavyret: 8 to a total of 16 weeks* based on genotype, prior treatment history, and cirrhosis status
Sofosbuvir/velpatasvir (Epclusa AG)/ Sofosbuvir/ledipasvir (Harvoni AG)/Sovaldi/Vosevi: up to a total of 24 weeks* based on genotype, prior treatment history, and cirrhosis status
*(*Approved duration should be consistent with FDA or AASLD/IDSA treatment guidelines for chronic hepatitis C infection)*

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

II. Continued Therapy

A. Chronic Hepatitis C Infection (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Mavyret for treatment of chronic HCV infection and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g., decreased HCV RNA level, no unacceptable toxicity);
3. Prescribed regimen and dose are consistent with an FDA or AASLD-IDSA treatment guidelines for chronic hepatitis C infection;
4. Member has none of limitations from Section III. Diagnoses/Indications for which coverage is NOT authorized.

Approval duration:
Mavyret: 8 to a total of 16 weeks* based on genotype, prior treatment history, and cirrhosis status
Sofosbuvir/velpatasvir (Epclusa AG)/ Sofosbuvir/ledipasvir (Harvoni AG)/Sovaldi/Vosevi: up to a total of 24 weeks* based on genotype, prior treatment history, and cirrhosis status
Viekira Pak: 12 weeks* based on genotype, prior treatment history, and cirrhosis status

Zepatier: up to a total of 16 weeks* based on genotype, prior treatment history, and cirrhosis status *(*Approved duration should be consistent with FDA or AASLD/IDSA treatment guidelines for chronic hepatitis C infection)*

III. Diagnoses/Indications for which coverage is NOT authorized:

- **A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – AZ.CP.PMN.53 for Arizona Medicaid;
- **B.** The member life expectancy is less than 12 months and cannot be remediated by treating the HCV infection, by transplantation or by other directed therapy;
- **C.** The member was non-adherent to the initial DAA treatment regimen as evidenced by medical records and/or pharmacy prescription claims;
- **D.** The treatment is considered an experimental service as defined in A.A.C. R9-22-203. Based on current evidence, this includes more than one retreatment with a DAA and requested retreatment regimens that include more than one DAA;
- **E.** Monotherapy of sofosbuvir (Sovaldi);
- **F.** DAA dosages greater than the FDA approved maximum dosage;
- **G.** Grazoprevir/elbasvir (Zepatier) if the NS5A polymorphism testing has not been completed and submitted with the prior authorization request;
- **H.** Members who do not agree to adhere to the proposed course of treatment, including participating in a treatment adherence program if applicable;
- **I.** Members currently using a potent P-gp inducer drug (St. John's wart, rifampin, carbamazepine, ritonavir, tipranavir, etc.);
- **J.** Lost or stolen medications absent of good cause;
- **K.** Fraudulent use of HCV medications.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AASLD: American Association for the Study of Liver Diseases
AG: Authorized Generic
AHCCCS: Arizona Health Care Cost Containment System
HBV: hepatitis B virus
HCC: hepatocellular carcinoma
HCV: hepatitis C virus
FDA: Food and Drug Administration
IDSA: Infectious Diseases Society of America
IFN: interferon
NS3/4A, NS5A/B: nonstructural protein
PegIFN: pegylated interferon
RBV: ribavirin
RNA: ribonucleic acid

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Epclusa
  - Contraindication(s): Epclusa and RBV combination regimen is contraindicated in patients for whom RBV is contraindicated. Refer to the RBV prescribing information for a list of contraindications for RBV.
  - Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV
- Harvoni
  - Contraindication(s): if used in combination with RBV, all contraindications to RBV also apply to Harvoni combination therapy.
  - Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV
- Mavyret
  - Contraindication(s):
    - Patients with severe hepatic impairment (Child-Pugh B or C)
    - Co-administration with atazanavir or rifampin
  - Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV
- Sovaldi
  - Contraindication(s): when used in combination with peginterferon alfa/RBV or RBV alone, all contraindications to peginterferon alfa and/or RBV also apply to Sovaldi combination therapy.
  - Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV
- Viekira Pak
  - Contraindication(s): Viekira Pak is contraindicated in:
    - Patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity
    - If Viekira is administered with RBV, the contraindications to RBV also apply to this combination regimen. Refer to the RBV prescribing information for a list of contraindications for RBV.
    - Co-administration with drugs that are:
      - Highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events
      - Moderate or strong inducers of CYP3A and strong inducers of CYP2C8 and may lead to reduced efficacy of Viekira Pak
      - Strong inhibitors of CYP2C8 and may increase dasabuvir plasma concentrations and the risk of QT prolongation
    - Patients with known hypersensitivity to ritonavir (e.g., toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome).
  - Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV

- Vosevi
  - Contraindication(s): coadministration with rifampin
  - Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV
- Zepatier
  - Contraindication(s):
    - Patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to the expected significantly increased grazoprevir plasma concentration and the increased risk of alanine aminotransferase (ALT) elevations or those with any history of hepatic decompensation due to the risk of hepatic decompensation
    - With inhibitors of organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitors that are known or expected to significantly increase grazoprevir plasma concentrations, strong CYP3A inducers, and efavirenz
    - If Zepatier is administered with RBV, the contraindications to RBV also apply.
  - Boxed warning(s): risk of hepatitis B virus reactivation in patients coinfected with HCV and HBV

Appendix C: General Information

- Child-Pugh Score:

	1 Point	2 Points	3 Points
Bilirubin	Less than 2 mg/dL Less than 34 umol/L	2-3 mg/dL 34-50 umol/L	Over 3 mg/dL Over 50 umol/L
Albumin	Over 3.5 g/dL Over 35 g/L	2.8-3.5 g/dL 28-35 g/L	Less than 2.8 g/dL Less than 28 g/L
INR	Less than 1.7	1.7 - 2.2	Over 2.2
Ascites	None	Mild / medically controlled	Moderate-severe / poorly controlled
Encephalopathy	None	Mild / medically controlled Grade I-II	Moderate-severe / poorly controlled. Grade III-IV

Child-Pugh class is determined by the total number of points: A = 5-6 points; B = 7-9 points; C = 10-15 points

Appendix D: Direct-Acting Antivirals for Treatment of HCV Infection

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Epclusa*	Velpatasvir	Sofosbuvir			

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)	CYP3A Inhibitor
Harvoni*	Ledipasvir	Sofosbuvir			
Mavyret*	Pibrentasvir			Glecaprevir	
Sovaldi		Sofosbuvir			
Viekira Pak*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Vosevi*	Velpatasvir	Sofosbuvir		Voxilaprevir	
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs

V. Dosage and Administration

AASLD/IDSA treatment guidelines for chronic hepatitis C infection are updated at irregular intervals; refer to the most updated AASLD/IDSA guideline for most accurate treatment regimen. Available at: https://www.hcvguidelines.org/

VI. Product Availability

- Epclusa
  - Tablets: sofosbuvir 400 mg with velpatasvir 100 mg, sofosbuvir 200 mg with velpatasvir 50 mg
- Epclusa AG
  - Tablets: sofosbuvir 400 mg with velpatasvir 100 mg
- Harvoni
  - Tablets: 90 mg of ledipasvir and 400 mg of sofosbuvir; 45 mg of ledipasvir and 200 mg of sofosbuvir
  - Oral pellets: 45 mg of ledipasvir and 200 mg of sofosbuvir; 33.75 mg of ledipasvir and 150 mg of sofosbuvir
- Harvoni AG
  - Tablets: 90 mg of ledipasvir and 400 mg of sofosbuvir
- Mavyret
  - Tablets: glecaprevir 100 mg and pibrentasvir 40 mg
  - Oral pellet: glecaprevir 50 mg and pibrentasvir 20 mg
- Sovaldi
  - Tablets: 400 mg, 200 mg
  - Oral pellets: 200 mg, 150 mg
- Viekira Pak
  - Tablet: paritaprevir 75 mg, ritonavir 50 mg, ombitasvir 12.5 mg
  - Tablet: dasabuvir 250 mg

**Viekira Pak is dispensed in a monthly carton for a total of 28 days of therapy. Each monthly carton contains four weekly cartons. Each weekly carton contains seven daily dose packs*

- Vosevi
  - Tablet: sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg
- Zepatier
  - Tablet: grazoprevir 100 mg with elbasvir 50 mg

VII. References

1. Epclusa Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; June 2021. Available at http://www.gilead.com/~/media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf?la=en. Accessed October 1, 2021.
2. Harvoni Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; March 2020. Available at http://www.harvoni.com/. Accessed October 1, 2021.
3. Mavyret Prescribing Information. North Chicago, IL: AbbVie Inc.; June 2021. Available at: www.mavyret.com. Accessed October 1, 2021.
4. Sovaldi Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; March 2020. Available at: https://www.gilead.com/~/media/files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf. Accessed October 1, 2021.
5. Viekira Pak Prescribing Information. North Chicago, IL: Abbvie Pharmaceuticals Corp; December 2019. Available at https://www.rxabbvie.com/. Accessed October 1, 2021.
6. Vosevi Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; November 2019. Available at: www.vosevi.com. Accessed October 1, 2021.
7. Zepatier Prescribing Information. Whitehouse Station, NJ: Merck and Company, Inc.; December 2019. Available at http://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf. Accessed October 1, 2021.
8. Arizona Health Care Cost Containment System (AHCCCS), AHCCCS Medical Policy Manual (AMPM), Policy 320-N, Hepatitis C Prior Authorization Requirements for Direct Acting Antiviral Medication Treatment, revisions effective 10/1/21.
9. American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. Available at: https://www.hcvguidelines.org/. Accessed October 1, 2021.
10. CDC. Hepatitis C Q&As for health professionals. Last updated August 7, 2020. Available at: https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. Accessed October 1, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date

Policy created. Safety criteria were applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Exception made to require Hep B screening for all patients prior to treatment to ensure that proper risk reduction measures are taking, though this is not specifically addressed in boxed warning.	08.15.17	08.17
Initial approval criteria was clarified from "up to a total of 16 weeks" to "8 to up to a total of 16 weeks" per Corporate P&T feedback.	09.05.17	11.17
Added dosing recommendations for persons with liver or kidney transplants.	08.28.18	08.18
Added Epclusa AG as preferred; Added age restriction for Mavyret and Epclusa AG requests; Added approval duration for Epclusa AG; Updated DAA chart; Updated Section V. Dosage and Administration; Moved "Required Documentation for Submission of a HCV Prior Authorization Request" up in the document; Added B. Hepatitis C Reatreatment Requirements from AHCCCS AMPM 320-N; Removed I.A.2. Confirmed HCV genotype is one of the following (a, b, or c) and replaced with "Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Section V Dosage and Administration for reference*)"	11.15.19	11.19
Pediatric dosing updated for Mavyret; RT4: updated dosing recommendations to 8 weeks total duration of therapy for treatment naive HCV with compensated cirrhosis across all genotypes (1-6).	1.8.2020	1.15.2020
Annual review; References updated; No clinical updates.	07.07.20	07.20
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21
Annual review; References updated; No clinical updates.	07.24.21	07.21
Updated policy based on AHCCCS AMPM 320-N update effective 10/1/2021; combined preferred (AZ.CP.PHAR.44) and non-preferred hepatitis C treatments (AZ.CP.PHAR.400) except for ribavirin (CP.PHAR.141) into one policy for Direct Acting Antiviral (DAA) medications for treatment of Hepatitis C Virus (HCV); references reviewed and updated.	10.01.21	10.21
RT4: updated criteria for Mavyret pediatric age expansion to 3 years and older along with pediatric dosing and new	10.12.21	11.21

oral pellet dosage formulation; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.