

**Clinical Policy: Infectious Disease Agents: Antivirals - Herpes**

Reference Number: OH.PHAR.PPA.72

Effective Date: 01/01/2020

Last Review Date: N/A

Line of Business: Medicaid

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description:**

**INFECTIOUS DISEASE AGENTS: ANTIVIRALS - HERPES**

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACYCLOVIR (generic of Zovirax®) VALACYCLOVIR (generic of Valtrex®)	FAMCICLOVIR (generic of Famvir®) SITAVIG® buccal tablets (acyclovir)

**FDA Approved Indication(s):**

Antivirals are indicated for the treatment of:

- herpes genitalis
- herpes genitalis prophylaxis
- herpes labialis
- herpes simplex virus infection
- herpes zoster (shingles) infection
- varicella (chickenpox) infection

**Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation®, that Famvir and Sitavig are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. PA Required Agents (must meet all):**

1. FDA-approved or supported by standard pharmacopeias;
2. Age ≥ 18 years;
3. Documentation that there have been therapeutic failures to no less than a 3 day trial of at least one medication not requiring prior approval UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
  - Allergies to all medications not requiring prior approval.
  - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
  - History of unacceptable/toxic side effects to medications not requiring prior approval.

**Approval duration:** For the duration of the prescription (up to 180 days).

**B. Other diagnoses/indications:**

1. There are no pharmacy and therapeutic committee approved off-label use criteria for the diagnosis;
2. Use is supported by one of the following (a, b, or c):
  - a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1 or 2A;
  - b. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
    - i. Adequate representation of the member’s clinical characteristics, age, and diagnosis;
    - ii. Adequate representation of the prescribed drug regimen;
    - iii. Clinically meaningful outcomes as a result of the drug therapy in question;
    - iv. Appropriate experimental design and method to address research questions;
  - c. Micromedex DrugDex<sup>®</sup> with strength of recommendation Class I, IIa, or IIb;
3. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
4. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist for the same indication at maximum indicated doses, unless no such drugs exist, at maximum indicated doses, unless contraindicated or clinically significant adverse effect are experienced;
5. Dosing regimen and duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature.

**Approval duration:** For the duration of the prescription (up to 180 days).

**II. Diagnoses/Indications for which coverage is NOT authorized:**

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 policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

**III. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ER: Extended Release

FDA: Food and Drug Administration

PA: Prior Authorization

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acyclovir (Zovirax)	<b>Herpes Labialis</b> Initial episode: 400 mg 3 times per day for 5 to 10 days Chronic suppression: 400 mg twice daily	4,000 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acyclovir (Zovirax) - continued	<p style="text-align: center;"><b>Herpes Zoster</b></p> 800 mg every 4 hours, 5 times a day for 7 to 10 days <p style="text-align: center;"><b>Varicella</b></p> 800 mg 4 times per day for 5 days <p style="text-align: center;"><b>Herpes Genitalis</b></p> Initial episode: 200 mg 5 times daily for 7-10 days OR 400 mg 3 times daily for 7-10 days Recurrence: 200 mg every 4 hours, 5 times a day for 5 days OR 400 mg 3 times per day for 5 days OR 800 mg 3 times per day for 2 days OR 800 mg twice daily for 5 days Chronic suppression: 400 mg twice daily	4,000 mg/day
valacyclovir (Valtrex)	<p style="text-align: center;"><b>Herpes Labialis</b></p> 2 g every 12 hours for 2 doses <p style="text-align: center;"><b>Herpes Zoster</b></p> 1 g 3 times daily for 7 days <p style="text-align: center;"><b>Varicella</b></p> 1 g 3 times daily for 5 to 7 days <p style="text-align: center;"><b>Herpes Genitalis</b></p> Initial episode: 1 g twice daily for 10 days Recurrence: 500 mg twice daily for 3 days OR 1 g once daily for 5 days Chronic suppression: 1 g once daily	4 g/day for one-day treatment regimens or 3 g/day for regimens lasting longer than one day

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Acyclovir Hypersensitivity
  - Valacyclovir Hypersensitivity
  - Milk Protein Hypersensitivity
  - Famciclovir Hypersensitivity
  - Penciclovir Hypersensitivity

**IV. Dosage and Administration**

- Varies by drug product. See FDA approved dosing and administration AND Appendix B.

**V. Product Availability**

Drug Name	Availability
Acyclovir	Capsules: 200 mg
Acyclovir	Oral suspension: 200 mg/5 mL
Acyclovir	Powder for injection: 500 mg
Acyclovir	Solution for injection: 50 mg/mL, 500 mg/10 mL, 1000 mg/20 mL
Acyclovir	Tablets: 400 mg, 800 mg
Acyclovir	Topical cream: 5% in a 5 g tube
Acyclovir	Topical Ointment: 5% in a 5 g, 15 g, and 30 g tube
Famciclovir	Tablets: 125 mg, 250 mg, 500 mg
Sitavig	Buccal Tablets: 50 mg
Valacyclovir	Tablets: 500 mg, 1 g

**VI. References**

- Acyclovir. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 13, 2019.
- Famciclovir. Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 13, 2019.
- Sitavig (acyclovir) [package insert]. Charleston, SC; EPI Health LLC; 2015.
- Valacyclovir Clinical Pharmacology. Elsevier. Tampa, FL. Available at <https://www.clinicalpharmacology-ip.com>. Accessed November 13, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A

**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.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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