

Clinical Policy: Famciclovir (Famvir)

Reference Number: HIM.PA.63

Effective Date: 12/14

Last Review Date: 08/17

Line of Business: Health Insurance Marketplace

[Revision Log](#)

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

Description

Famciclovir (Famvir®), a prodrug of penciclovir, is a nucleoside analog DNA polymerase inhibitor.

FDA approved indication

Famvir is indicated for:

- Immunocompetent adult patients
 - Herpes labialis (cold sores)
 - Treatment of recurrent episodes
 - Genital herpes
 - Treatment of recurrent episodes
 - Suppressive therapy of recurrent episodes
 - Herpes zoster (shingles)
- Human immunodeficiency virus (HIV)-infected adult patients
 - Treatment of recurrent episodes of orolabial or genital herpes

Limitations of use: The efficacy and safety of Famvir have not been established for:

- Patients < 18 years of age
- Patients with first episode of genital herpes
- Patients with ophthalmic zoster
- Immunocompromised patients other than for the treatment of recurrent orolabial or genital herpes in HIV-infected patients.
- Black and African American patients with recurrent genital herpes

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Herpes Labialis, Genital Herpes, and Herpes Zoster (must meet all):

1. Diagnosis of herpes labialis, genital herpes, or herpes zoster;
2. Failure of valacyclovir or acyclovir unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed (a, b, or c):
 - a. Herpes labialis (i or ii):
 - i. Immunocompetent: 1500 mg as a single dose (3 tablets);
 - ii. Immunocompromised (HIV-infected): 500 mg twice daily for up to 10 days (2 tablets/day).

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- b. Genital herpes (i or ii):
 - i. Recurrent episode (a or b):
 - 1. Immunocompetent: 1000 mg twice daily for one day (4 tablets);
 - 2. Immunocompromised (HIV-infected): 500 mg twice daily for up to 10 days (2 tablets/day);
 - ii. Suppressive therapy (a or b):
 - a) Immunocompetent: 250 mg twice daily (2 tablets/day);
 - b) Immunocompromised (HIV-infected): 500 mg twice daily (2 tablets/day);
- c. Herpes zoster: 500 mg three times daily (3 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications

- 1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Herpes Labialis, Genital Herpes, and Herpes Zoster (must meet all):

- 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- 2. Documentation of positive response to therapy;
- 3. Dose does not exceed (a, b, or c):
 - a. Herpes labialis (i or ii):
 - i. Immunocompetent: 1500 mg as a single dose (3 tablets);
 - ii. Immunocompromised (HIV-infected): 500 mg twice daily for up to 10 days (2 tablets/day);
 - b. Genital herpes (i or ii):
 - i. Recurrent episode (1 or 2):
 - 1. Immunocompetent: 1000 mg twice daily for one day (4 tablets);
 - 2. Immunocompromised (HIV-infected): 500 mg twice daily for up to 10 days (2 tablets/day);
 - ii. Suppressive therapy (a or b):
 - a) Immunocompetent: 250 mg twice daily (2 tablets/day);
 - b) Immunocompromised (HIV-infected): 500 mg twice daily (2 tablets/day);
 - c. Herpes zoster: 500 mg three times daily (3 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

- 1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

- 2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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

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- 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 policy – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

HIV: human immunodeficiency virus

V. References

1. Famvir Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp.; September 2016. Available at: <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/Famvir.pdf> . Accessed January 18, 2017.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016 Available at: www.clinicalpharmacology-ip.com/. Accessed January 18, 2017.
3. Facts & Comparisons eAnswers [database online]. Available at <http://online.factsandcomparisons.com>. Accessed June 2016.
4. Centers for Disease Control and Prevention. 2015 Sexually transmitted diseases treatment guidelines: genital herpes. Available at: <http://www.cdc.gov/std/tg2015/herpes.htm>. Published June 4, 2015. Updated June 8, 2015. Accessed March 27, 2017.
5. Dworkin RH, Johnson RW, Breuer J, et al. Recommendations for management of herpes zoster. *Clinical Infectious Diseases*. 2007; 44(Suppl 1): S1-S26.
6. Emmert DH. Treatment of common cutaneous herpes simplex virus infections. *Am Fam Physician*. 2000; 61(6): 1697-1704.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Previous Revision-new format	08/16	08/16
Converted to new template Removed age restriction as it is not an absolute contraindication per FDA labeling Added max dosing criteria Added references	04/17	08/17

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

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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.

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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.

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