

Clinical Policy: Famciclovir (Famvir®)
Reference Number: CP.PMN.26
Effective Date: 09/06
Last Review Date: 08/17
Line of Business: Medicaid

[Revision Log](#)

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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

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

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

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that Famvir is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Herpes Labialis (Cold Sores) (must meet all):

1. Age \geq 18 years;
1. Diagnosis of herpes labialis (cold sores);
2. Prescribed for treatment of recurrent episodes;

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- ~~2-3.~~ Member meets one of the following (a¹ or 2^b):
- a. Failure of valacyclovir;
 - b. If contraindicated to Unable to use valacyclovir, due to contraindication and has failure of therapy with acyclovir, unless contraindicated or clinically significant adverse effects are experienced;
- ~~3.~~ Documentation indicates that treatment is for a recurrent episode of orolabial herpes;
- ~~4.~~ Request Dose does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit:
- a. Immunocompetent: 1500 mg as a single dose (3 tablets);
 - ~~4-b.~~ Immunocompromised (HIV-infected): 500 mg twice daily ~~+1000 mg/day~~ for up to 10 days (2 tablets/day). -

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Approval duration: 1 day for immunocompetent patients; up to 10 days for immunocompromised patients

Immunocompetent: 1500 mg one time dose
Immunocompromised: (HIV infected): 500 mg twice daily for 7-10 days

B. Genital Herpes (must meet all):

- ~~1.~~ Age \geq 18 years;
- ~~1.~~ Diagnosis of genital herpes;
2. Member meets one of the following (a¹ or b²):
- a. Failure of valacyclovir;
 - b. If contraindicated to Unable to use valacyclovir, due to contraindication and has failed therapy with of acyclovir, unless contraindicated or clinically significant adverse effects are experienced;
- ~~3.~~ Request Dose does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit:
- a. Initial episode: 250 mg three times daily ~~750 mg/day~~ for up to 10 days (3 tablets/day);
 - b. Recurrent episode:
 - i. Immunocompetent: 1000 mg twice daily for one day (4 tablets);
 - ii. Immunocompromised (HIV-infected): 500 mg twice daily ~~+1000 mg/day~~ for up to 10 days (2 tablets/day);
 - c. Suppressive therapy:
 - i. Immunocompetent: 250 mg twice daily ~~500 mg/day~~ (2 tablets/day);
 - ~~3-ii.~~ Immunocompromised (HIV-infected): 500 mg twice daily ~~+1000 mg/day~~ (2 tablets/day). -

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Approval duration:
Initial episode: up to 10 days
Recurrent episode: 1 day for immunocompetent patients; up to 10 days for immunocompromised patients
Suppressive therapy: 6 months

Initial episode: up to 250mg three times daily for 7-10 days
Immunocompetent:
Recurrent episode: up to 1000mg twice daily for one day

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~~Suppressive therapy: up to 250mg twice daily for 6 months~~
~~Immunocompromised (HIV-infected):~~
~~Recurrent episode: up to 500mg twice daily for 7-14 days~~
~~Suppressive episode: up to 500mg twice daily for 6 months~~

C. Herpes Zoster (must meet all):

- ~~1. Age \geq 18 years;~~
- ~~1. Diagnosis of herpes zoster;~~
2. Member meets one of the following (a¹ or b)²:
 - a. Failure of valacyclovir;
 - b. If contraindicated to Unable to use valacyclovir, due to contraindication and has failure of ed therapy with acyclovir, unless contraindicated or clinically significant adverse effects are experienced;
3. Request Dose does not exceed 500 mg three times daily 1500 mg/day (3 tablets/day) FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: ~~up to 500 mg three times daily for 7 days~~

D. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Herpes Labialis (must meet all):

- ~~1. Previously received medication via Centene benefit or member has previously met initial approval criteria;~~
- ~~2. Documentation of positive response to therapy;~~
- ~~3. If request is for a dose increase, new dose does not exceed:~~
 - a. Immunocompetent: 1500 mg as a single dose (3 tablets);
 - b. Immunocompromised (HIV-infected): 500 mg twice daily 1000 mg/day for up to 10 days (2 tablets/day).

Approval duration: 1 day for immunocompetent patients; up to 10 days for immunocompromised patients

A.B. Genital Herpes (must meet all):

- ~~1. Currently/Previously received/receiving medication via Centene benefit or member has previously met initial approval criteria/Currently receiving therapy for suppression of recurrent genital herpes per provider's documentation or pharmacy claims record;~~
- ~~2. Documentation of positive response to therapy;~~
- ~~3. If request is for a dose increase, new dose does not exceed/Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit;~~
 - a. Recurrent episode:
 - i. Immunocompetent: 1000 mg twice daily for one day (4 tablets);
 - ii. Immunocompromised (HIV-infected): 500 mg twice daily 1000 mg/day for up to 10 days (2 tablets/day);

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b. Suppressive therapy:

- i. Immunocompetent: 250 mg twice daily~~500 mg/day~~ (2 tablets/day);**
- ii. Immunocompromised (HIV-infected): 500 mg twice daily~~1000 mg/day~~ (2 tablets/day).**

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Approval duration: -6 months (for recurrent episodes, no more than 3 treatments/6 months; members exceeding this may receive additional treatments upon submission of documentation supporting recurrence)

Immunocompetent: up to 250mg twice daily

Immunocompromised (HIV infected): up to 500mg twice daily

(No more than 12 months of treatment total)

C. Herpes Zoster (must meet all):

- 1. Previously received medication via Centene benefit or member has previously met initial approval criteria;
- 2. Request is for a new occurrence of herpes zoster since the last request;
- 3. Dose does not exceed 500 mg three times daily (3 tablets/day).

Approval duration: 7 days

B-D. 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 CP.PMN.53 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:

- 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 – CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

HIV: human immunodeficiency virus

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Herpes labialis (cold sores)	<i>Immunocompetent:</i> 1500 mg as a single dose <i>HIV-infected:</i> 500 mg twice daily for 7 days	<i>Immunocompetent:</i> 1500 mg/treatment <i>HIV-infected:</i> 1000 mg/day
Genital herpes- treatment of recurrent episodes	<i>Immunocompetent:</i> 1000 mg twice daily for 1 day <i>HIV-infected:</i> 500 mg twice daily for 7 days	<i>Immunocompetent:</i> 2000 mg/treatment <i>HIV-infected:</i> 1000 mg/day

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Genital herpes- suppressive therapy	250 mg twice daily	500 mg/day
Herpes zoster	500 mg every 8 hours for 7 days	1500 mg/day

VI. Product Availability

Tablets: 125 mg, 250 mg, 500 mg

VII. Workflow Document



CP.PMN.26 Famvir
Workflow.docx

VIII. References

1. Famvir Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corp.; April 2013/September 2016. Available at: <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/Famvir.pdf> <https://dailymed.nlm.nih.gov/dailymed/>. Accessed June 2016/March 27, 2017.
2. Centers for Disease Control and Prevention. Famciclovir. In: Clinical Pharmacology. Tampa, FL: Gold Standard; 2015. Available at <http://www.clinicalpharmacology-ip.com/>. Accessed June 2016.
3. Facts & Comparisons eAnswers accessed January 2015. <http://online.factsandcomparisons.com>.
4. Albrecht MA. Treatment of genital herpes simplex virus infection. Hirsch MS. (Ed), In UpToDate, Waltham MA. Accessed June 2016.
2. 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 June 23, 2016/March 27, 2017.
3. Dworkin RH, Johnson RW, Breuer J, et al. Recommendations for management of herpes zoster. Clinical Infectious Diseases. 2007; 44(Suppl 1): S1-S26.
- 5.4. 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
Updated the “FDA Labeled Indications” and “Special Instructions” sections. Updated reference section to reflect current literature search.	02/10	02/10
Added “Approval” timeframes. Added “or” valacyclovir as a prior trial and failure condition. Added criteria point “Lack of acyclovir or valacyclovir compliance does not constitute treatment failure.” References updated to reflect current literature search.	02/11	02/11
Converted to new template;	12/15	02/16

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Modified guideline by listing the approval criteria by indication; Modified criteria for genital herpes to require only the prior failure of acyclovir in accordance with FDA approved indication; Clarified duration of approval for each indication and provided treatment duration allowance per HIV-treated guideline Added continuity of care approval criteria Updated reference section to reflect current literature search.		
Modified criteria for all agents to require trial/failure of Valacyclovir, and acyclovir only in members intolerant to valacyclovir. Rationale: Valacyclovir is most comparable to Famvir with regards to dosing and bioavailability. Valacyclovir is a prodrug of acyclovir, with improved bioavailability; therefore it's not clinically logical for members who have failed valacyclovir to be required to fail acyclovir; Modified criteria to allow famvir for initial, recurrent and suppressive treatment of genital herpes per CDC; References updated to reflect current literature search.	07/16	08/16
<u>Clinical changes to criteria</u> <u>Genital herpes: Added recurrent episode treatment to continued therapy criteria as genital herpes is a chronic disease with episodes that can recur multiple times a year. Removed hard stop at 12 months as there is no data supporting inefficacy/unsafe use of suppressive therapy past that duration.</u> <u>Herpes labialis: Added criteria for continued therapy as this disease is chronic and may recur.</u> <u>Herpes zoster: Added criteria for continued therapy as it can recur.</u> <u>Non-clinical changes to criteria</u> <u>Removed age restriction as it is not an absolute contraindication per PI</u>	04/17	08/17

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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

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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.

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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.

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Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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