Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2018**
Policy Number:	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name:	**HC Approval Date:**

Type of Submission – Check all that apply:

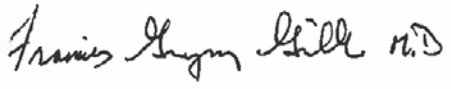
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and will not be replaced:

Prior Authorization is no longer required

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Famciclovir (Famvir)

Reference Number: PA.CP.PMN.26
Effective Date: 01/18
Last Review Date: 08/17 Revision Log

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 office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that Famvir is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of herpes labialis (cold sores);
2. Prescribed for treatment of recurrent episodes;
3. Member meets one of the following (a or b):
   a. Failure of valacyclovir;
   b. If contraindicated to valacyclovir, failure of acyclovir unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed:

a. Immunocompetent: 1500 mg as a single dose (3 tablets);
b. Immunocompromised (HIV-infected): 500 mg twice daily for up to 10 days (2 tablets/day).

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

B. Genital Herpes (must meet all)**:**
1. Diagnosis of genital herpes;
2. Member meets one of the following (a or b):
   a. Failure of valacyclovir;
   b. If contraindicated to valacyclovir, failure of acyclovir unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed:
   a. Initial episode:
      i. Immunocompetent: 250 mg three times daily for up to 10 days (3 tablets/day);
      ii. Immunocompromised (HIV-infected): 500mg twice daily for up to 14 days (2 tablets/day);
   b. Recurrent episode:
      i. Immunocompetent: 1000 mg twice daily for one day (4 tablets);
      ii. Immunocompromised (HIV-infected): 500 mg twice daily for up to 1 days (2 tablets/day);
   c. Suppressive therapy:
      i. Immunocompetent: 250 mg twice daily (2 tablets/day);
      ii. Immunocompromised (HIV-infected): 500 mg twice daily (2 tablets/day).

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**

C. Herpes Zoster (must meet all)**:**
1. Diagnosis of herpes zoster;
2. Member meets one of the following (a or b):
   a. Failure of valacyclovir;
   b. If contraindicated to valacyclovir, failure of acyclovir unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 500 mg three times daily (3 tablets/day).

Approval duration: **7 days**

D. Other diagnoses/indications
1. Refer to PA.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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PA.01) applies;
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 for up to 10 days (2 tablets/day).

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

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

1. Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PA.01) applies;
2. Documentation of positive response to therapy;
3. Healing is incomplete after 10 days of therapy;
4. If request is for a dose increase, new dose does not exceed:
   a. Recurrent episode:
      i. Immunocompetent: 1000 mg twice daily for one day (4 tablets);
      ii. Immunocompromised (HIV-infected): 500 mg twice daily for up to 10 days (2 tablets/day);
   b. Suppressive therapy:
      i. Immunocompetent: 250 mg twice daily (2 tablets/day);
      ii. Immunocompromised (HIV-infected): 500 mg twice daily (2 tablets/day).

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)

C. Herpes Zoster (must meet all)**:**

1. Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PA.01) applies;
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**

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PA.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.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 – PA.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)	*Immunocompetent*: 1500 mg as a single dose *HIV-infected*: 500 mg twice daily for 7 days	*Immunocompetent*: 1500 mg/treatment *HIV-infected*: 1000 mg/day
Genital herpes- treatment of recurrent episodes	*Immunocompetent*: 1000 mg twice daily for 1 day *HIV-infected*: 500 mg twice daily for 7 days	*Immunocompetent*: 2000 mg/treatment *HIV-infected*: 1000 mg/day
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. 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 March 27, 2017.
2. 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.
3. Dworkin RH, Johnson RW, Breuer J, et al. Recommendations for management of herpes zoster. Clinical Infectious Diseases. 2007; 44(Suppl 1): S1-S26.
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