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

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
  o Herpes labialis (cold sores)
    ▪ Treatment of recurrent episodes
  o Genital herpes
    ▪ Treatment of recurrent episodes
    ▪ Suppressive therapy of recurrent episodes
  o Herpes zoster (shingles)
• Human immunodeficiency virus (HIV)-infected adult patients
  o 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 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. Diagnosis of herpes labialis (cold sores);
      2. Prescribed for treatment of recurrent episodes;
      3. Member meets one of the following (a or b):
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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: 250 mg three times daily 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 for up to 10 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 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 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 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. 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 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

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herpes labialis (cold sores)</td>
<td><em>Immunocompetent</em>: 1500 mg as a single dose</td>
<td><em>Immunocompetent</em>:</td>
</tr>
<tr>
<td></td>
<td><em>HIV-infected</em>: 500 mg twice daily for 7 days</td>
<td>1500 mg/treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>HIV-infected</em>: 1000 mg/day</td>
</tr>
<tr>
<td>Genital herpes- treatment of recurrent episodes</td>
<td><em>Immunocompetent</em>: 1000 mg twice daily for 1 day</td>
<td><em>Immunocompetent</em>:</td>
</tr>
<tr>
<td></td>
<td><em>HIV-infected</em>: 500 mg twice daily for 7 days</td>
<td>2000 mg/treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>HIV-infected</em>: 1000 mg/day</td>
</tr>
<tr>
<td>Genital herpes- suppressive therapy</td>
<td>250 mg twice daily</td>
<td>500 mg/day</td>
</tr>
<tr>
<td>Herpes zoster</td>
<td>500 mg every 8 hours for 7 days</td>
<td>1500 mg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability
Tablets: 125 mg, 250 mg, 500 mg

VII. Workflow Document

CP.PMN.26 Famvir Workflow.docx

VIII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
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<tbody>
<tr>
<td>02/10</td>
<td>02/10</td>
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</table>

Updated the “FDA Labeled Indications” and “Special Instructions” sections.
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<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Updated reference section to reflect current literature search.</td>
<td></td>
<td>02/11</td>
</tr>
<tr>
<td>Added “Approval” timeframes.</td>
<td></td>
<td>02/11</td>
</tr>
<tr>
<td>Added “or” valacyclovir as a prior trial and failure condition.</td>
<td></td>
<td>12/15</td>
</tr>
<tr>
<td>Added criteria point “Lack of acyclovir or valacyclovir compliance does not constitute treatment failure.”</td>
<td>02/11</td>
<td>02/11</td>
</tr>
<tr>
<td>References updated to reflect current literature search.</td>
<td></td>
<td>12/15</td>
</tr>
<tr>
<td>Converted to new template; Modification of guideline by listing the approval criteria by indication;</td>
<td>07/16</td>
<td>08/16</td>
</tr>
<tr>
<td>Modified criteria for genital herpes to require only the prior failure of acyclovir in accordance with FDA approved indication;</td>
<td></td>
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<tr>
<td>Clarified duration of approval for each indication and provided treatment duration allowance per HIV-treated guideline</td>
<td></td>
<td></td>
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<tr>
<td>Added continuity of care approval criteria</td>
<td></td>
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</tr>
<tr>
<td>Updated reference section to reflect current literature search.</td>
<td>04/17</td>
<td>08/17</td>
</tr>
<tr>
<td>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.</td>
<td>04/17</td>
<td>08/17</td>
</tr>
<tr>
<td>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. Herpes labialis: Added criteria for continued therapy as this disease is chronic and may recur. Herpes zoster: Added criteria for continued therapy as it can recur. Removed age restriction as it is not an absolute contraindication per PI</td>
<td>04/17</td>
<td>08/17</td>
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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 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.

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