Clinical Policy: Acyclovir Buccal Tablet (Sitavig)
Reference Number: CP.CPA.153
Effective Date: 11.16.16
Last Review Date: 11.18
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Acyclovir buccal tablet (Sitavig®) is a synthetic purine nucleoside analogue active against herpes viruses.

FDA Approved Indication(s)
Sitavig is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

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 health plans affiliated with Centene Corporation® that Sitavig is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Herpes Labialis (must meet all):
      1. Diagnosis of recurrent herpes labialis (cold sores);
      2. Age ≥ 18 years;
      3. Documentation supports inability to use generic acyclovir tablets or capsules;
      4. Dose does not exceed 50 mg (single dose).
      
      Approval duration: One time

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy
   A. Herpes labialis (must meet all):
      1. Member meets initial approval criteria;
      2. Member previously responded positively to therapy;
      3. Dose does not exceed 50 mg (single dose).
      
      Approval duration: One time

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

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.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
Not applicable

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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
</table>
| acyclovir       | Initial Episode: 200 mg PO 5 times daily for 7-10 days OR 400 mg PO TID for 7-10 days  
                 | Recurrence: 400 mg PO TID for 5 days OR 800 mg PO BID for 5 days OR 800 mg TID for 2 days  
                 | Chronic suppression: 400 mg PO BID                  | 4000 mg/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
Not applicable

Appendix D: General Information
The clinical study cited in the manufacturer prescribing information evaluated Sitavig in patients with recurrent herpes labialis. All patients had at least 4 herpes episodes in the previous year.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of recurrent herpes labialis (cold sores)</td>
<td>50 mg PO applied as a single dose to the upper gum region</td>
<td>50 mg</td>
</tr>
</tbody>
</table>

VI. Product Availability
Buccal tablet: 50 mg
VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Converted to new template. Minor changes to verbiage and grammar. References updated.</td>
<td>01.10.17</td>
<td>11.17</td>
</tr>
<tr>
<td>4Q 2018 annual review: no significant changes; removed the requirement for documentation of an “immunocompetent adult” as this is under the purview of the prescriber; changed Approval duration from Length of Benefit to One time; updated Continued Therapy section to reflect the single-dose nature of Sitavig; references reviewed and updated.</td>
<td>07.11.18</td>
<td>11.18</td>
</tr>
</tbody>
</table>

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
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