Original Effective Date: 04/01/2012
Current Effective Date: 06/23/2023
Last P&T Approval/Version: 04/26/2023
Next Review Due By: 04/2024
Policy Number: C4349-A

Zovirax (acyclovir) Topical

PRODUCTS AFFECTED

Zovirax cream 5%, Zovirax ointment 5%, Acyclovir cream 5%, Acyclovir ointment 5%

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Herpes labialis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. HERPES VIRUS:
1. Documented diagnosis of herpes simplex viral infection
   AND
2. (a) Documentation of treatment failure, serious side effect, or contraindication to TWO of the following treatments: ORAL acyclovir, valacyclovir, or famciclovir
   AND

(b) Documentation of treatment failure, serious side effect, or contraindication to preferred/formulary topical acyclovir product
OR

3. ACYCLOVIR OINTMENT ONLY: Documentation request is for management of limited non-life-threatening mucocutaneous herpes simplex virus infections in an immunocompromised member

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
Initial authorization: 28 days, Continuation of therapy: NA

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Zovirax (acyclovir) cream-12 years of age and older
All others: 18 years of age and older

QUANTITY:
Maximum quantity limit per FDA label

PLACE OF ADMINISTRATION:
The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Topical

DRUG CLASS:
Antivirals - Topical

FDA-APPROVED USES:
Acyclovir cream: Indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older
Acyclovir ointment: Indicated for the management of initial genital herpes and in limited non-life threatening mucocutaneous HSV infections in immunocompromised patients

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Zovirax ointment is indicated for the initial treatment of genital herpes and in limited non-life-threatening mucocutaneous herpes simplex virus infections in immunocompromised patients. There has been no evidence of clinical benefit seen with the use of Zovirax ointment in treatment of herpes labialis in immunocompetent patients or in treatment of recurrent genital herpes infections.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Zovirax (acyclovir) topical are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to acyclovir include patients with known hypersensitivity to acyclovir, valacyclovir or any component of the formulation.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Zovirax cream 5% (5 grams), Zovirax ointment 5% (15gram, 30gram tube), acyclovir ointment 5% (5, 15, 30-gram tubes), acyclovir cream 5% (5 grams)

REFERENCES

1. Zovirax cream (acyclovir) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2021.
2. Zovirax ointment (acyclovir) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; October 2020.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Quantity FDA-Approved Uses References	Q2 2023
REVISION- Notable revisions: Required Medical Information	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file