

Pharmacy Policy Bulletin: J-1456 Zelsuvmi (berdazimer) – Commercial and Healthcare Reform	
Number: J-1456	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): None
Version: J-1456-001	Original Date: 04/03/2024
Effective Date: 07/28/2025	Review Date: 04/03/2024

Drugs Product(s):	Zelsuvmi (berdazimer)
FDA-Approved Indication(s):	Topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older

Background:	- Zelsuvmi is a nitric oxide releasing agent. The mechanism of action for the treatment of MC is unknown. - MC is a highly contagious viral skin infection caused by the molluscipoxvirus. It is characterized by skin-colored to red raised, pearl-like papules with a central, umbilicated viral core. MC causes pruritus. Scratching the papules causes them to spread leading to multiple papules forming in a line or cluster, swelling of the skin around the papules, and pain around the papules. Papules may persist for a few months to a few years, remaining contagious until resolved. MC has an incidence of approximately 8,000 cases per 100,000 individuals each year. Approximately 6 million Americans, primarily children, are infected. It is most common in children under 10 years of age. - Zelsuvmi is the first and only topical prescription medication that can be applied by patients, parents, or caregivers at home, outside of a physician's office, or other medical setting daily to treat MC. - Dispense equal amounts (0.5 mL) of gel from Tube A and Tube B onto the dosing guide. Mix together and immediately apply as an even thin layer once daily to each MC lesion for up to 12 weeks. - Prescribing Considerations: - Zelsuvmi has warnings or precautions for application site reactions, including allergic contact dermatitis.
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Approval Criteria

I. Initial Authorization

When a benefit, coverage of Zelsuvmi may be approved when both of the following criteria are met **(A. and B.):**

- A. The member is 1 year of age or older.
- B. The member has a diagnosis of molluscum contagiosum (ICD-10: B08.1).

II. Reauthorization

When a benefit, reauthorization of Zelsuvmi may be approved when all of the following criteria are met **(A. and B.):**

- A. The prescriber attests that the member has previously experienced complete or partial clearance of MC lesions with Zelsuvmi.
- B. The prescriber attest that an additional course of therapy is required for recurrence of MC.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 week authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Zelsuvmi [package insert]. Wilmington, Delaware: EPIH SPV, LLC; January 2024.
2. Olsen JR, Gallacher J, Piguet V, Francis NA. Epidemiology of molluscum contagiosum in children: a systematic review. *Fam Pract.* 2014;31(2):130-136.
3. Cleveland Clinic. Molluscum Contagiosum. Available at: <https://my.clevelandclinic.org/health/diseases/12175-molluscum-contagiosum>. Accessed February 7, 2024.
4. Centers for Disease Control and Prevention. Molluscum Contagiosum. Available at: <https://www.cdc.gov/poxvirus/molluscum-contagiosum/index.html>. Accessed on February 7, 2024.
5. American Academy of Dermatology. Molluscum Contagiosum: Diagnosis and Treatment. Available at: <https://www.aad.org/public/diseases/a-z/molluscum-contagiosum-treatment>. Accessed February 7, 2024.

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