Clinical Policy: Berdazimer (Zelsuvmi)

Reference Number: PA.CP.PMN.293
Effective Date: 05/2024
Last Review Date: 04/2024

Description
Berdazimer (Zelsuvmi™) is a nitric oxide releasing agent.

FDA Approved Indication(s)
Zelsuvmi is indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.

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 PA Health & Wellness® that Zelsuvmi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Molluscum Contagiosum (must meet all)**:**

1. Diagnosis of MC;
2. Age ≥ 1 year;
3. Member meets at least one of the following (a, b, c or d):
   a. Lesion is located in a sensitive area, such as facial and anogenital areas;
   b. Member has atopic dermatitis;
   c. Member has a weakened immune system*;
   **Example: patients with HIV/AIDS, patients taking immunosuppressive drugs for cancer, transplantation, etc., and children who have underdeveloped immunocompetency.*
   d. Member has extensive involvement or experiences bleeds, secondary infections or discomfort from the lesion, such as itchiness and pain;
4. Lesion did not resolve within six months since diagnosis or experiencing bleeding, itching, sexually active with genital involvement or complications (secondary infection in immunocompromised);
5. Zelsuvmi is not prescribed concurrently with any other pharmacologic treatments for MC *(see Appendix D)*;
6. Dose does not exceed one kit per 14 days

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Molluscum Contagiosum:

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   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): PA.CP.PMN.53

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 policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AIDS: acquired immunodeficiency syndrome
FDA: Food and Drug Administration
HIV: human immunodeficiency virus
MC: molluscum contagiosum

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- MC is a self-limited infection that usually resolves spontaneously in 6 to 12 months but may take years to disappear completely.
- MC lesions, known as Mollusca, are small, raised, and usually white, pink, or fleshcolored with a dimple or pit in the center. Lesions commonly range from 2 to 5 millimeters in diameter. They may become itchy, sore, red, and/or swollen. Mollusca may occur anywhere on the body including the face, neck, arms, legs, abdomen, and genital area, alone or in groups. The lesions are rarely found on the palms of the hands or the soles of the feet.
- Other topical and oral treatments for MC include but are not limited to cantharidin, podophyllotoxin, imiquimod, sinecatechins, topical retinoids, oral or topical zinc, ZymaDerm™, tea tree oil, cimetidine, other homeopathic treatments, other over-the-counter products, and other histamine H2 receptor antagonists.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MC	Mix 0.5 mL of gel each from Tube A and Tube B and apply topically to affected area QD for up to 12 weeks	See dosing regimen

VI. Product Availability

Topical gel: 10.3% berdazimer supplied as two tubes – Tube A contains berdazimer gel and Tube B contains hydrogel

VII. References

1. Zelsuvmi Prescribing Information. Wilmington, DE: EPIH SPV, LLC; January 2024. Available at: https://zelsuvmi.com/. Accessed January 15, 2024.
2. Browning JC, Enloe C, Cartwright M, et al. Efficacy and safety of topical nitric oxidereleasing berdazimer gel in patients with molluscum contagiosum: a phase 3 randomized clinical trial. JAMA Dermatol. 2022;158(8):871-878. doi:10.1001/jamadermatol.2022.2721
3. Sugarman JL, Hebert A, Browning JC, et al. Berdazimer gel for molluscum contagiosum: an integrated analysis of 3 randomized controlled trials. J Am Acad Dermatol. 2024;90(2):299- 308. doi:10.1016/j.jaad.2023.09.066
4. Edwards S, Boffa MJ, Janier M, et al. 2020 European guideline on the management of genital molluscum contagiosum. J Eur Acad Dermatol Venereol. 2021;35(1):17-26. doi:10.1111/jdv.16856

Reviews, Revisions, and Approvals	Date
Policy created	04/2024