Clinical Policy: Berdazimer (Zelsuvmi)

Reference Number: CP.PMN.293
Effective Date: 06.01.24
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

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

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 health plans affiliated with Centene Corporation® 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. One of the following (a, b, or c):
   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*;
   **Treatment is recommended in patients with HIV/AIDS, patients who are taking immunosuppressive drugs for cancer, transplantation, etc., and children who have underdeveloped immunocompetency.*
4. Lesion did not resolve within six months since diagnosis;
5. Member experiences bleeds or discomfort from the lesion, such as itchiness and pain;
6. Zelsuvmi is not prescribed concurrently with any other pharmacologic treatments for MC *(see Appendix D)*;
7. Dose does not exceed one kit per 14 days;
8. Requested duration of treatment does not exceed 12 weeks.

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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 flesh-colored 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 23, 2026
2. Browning JC, Enloe C, Cartwright M, et al. Efficacy and safety of topical nitric oxide-releasing 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	P&T Approval Date
Policy created	03.12.24	05.24
2Q 2025 annual review: no significant changes; references reviewed and updated.	01.29.25	05.25
2Q 2026 annual review: no significant changes; incorporated existing approval duration into criteria by adding requirement that requested duration of treatment does not exceed 12 weeks; references reviewed and updated. Added ICHRA line of business.	03.30.26	05.26

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 discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.