

Zelsuvmi™ (berdazimer)

Policy # 00949

Original Effective Date: 01/01/2026

Current Effective Date: 01/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: cantharidin (Ycanth®)† is addressed separately in medical policy 00875.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Zelsuvmi™† (berdazimer) topical gel to be **eligible for coverage**** when the patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility for Zelsuvmi (berdazimer) topical gel will be considered when the following criteria are met:

- Patient has a diagnosis of molluscum contagiosum (MC); AND
- Patient is 1 year of age and older; AND
- Patient will not use Zelsuvmi (berdazimer) in combination with another treatment modality for molluscum contagiosum, including but not limited to cryotherapy, curettage, podofilox or (cantharidin) Ycanth; AND
- Zelsuvmi (berdazimer) will not be used for the treatment of lesions located in or near the eyes, on the oral mucosa, or intravaginally; AND
- Patient meets one of the following criteria:
 - Patient has underlying eczema or atopic dermatitis; OR
 - Patient has extensive lesions or complications (e.g., infection, bleeding, itching, pain); OR
 - Patient has lesions in sensitive areas (e.g., face, external genitals); OR
 - Patient is immunocompromised (e.g., HIV, cancer therapy); OR
 - Lesions have persisted > 6 months.

*(Note: this specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Zelsuvmi (berdazimer) topical gel when the following patient selection criterion is NOT met to be **not medically necessary**.**

- Patient meets one of the following criteria:
 - Patient has underlying eczema or atopic dermatitis
 - Patient has extensive lesions or complications
 - Patient has lesions in sensitive areas
 - Patient is immunocompromised
 - Lesions have persisted > 6 months

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Zelsuvmi (berdazimer) topical gel when patient selection criteria are not met (except the criterion denoted above as **not medically necessary****) to be **investigational**.*

Background/Overview

Zelsuvmi is a nitric oxide releasing agent indicated in adult and pediatric patients 1 year of age and older for the topical treatment of molluscum contagiosum. It is the first FDA-approved topical drug indicated for MC that can be administered at home. Zelsuvmi is supplied in a carton containing a tube of berdazimer 10.3% topical gel and a tube of hydrogel which must be mixed in equal parts using the dosing guide provided. A thin layer of the mixture should be applied to each lesion once daily for up to 12 weeks and may be applied by the patient or a caregiver. The exact mechanism of action of Zelsuvmi in the treatment of MC is unknown.

Molluscum contagiosum is a common viral skin infection caused by the Poxviridae family that causes white-, pink-, or flesh-colored bumps/lesions in groups or alone on any part of the body. It can occur at any age but is most common in younger ages. This condition is contagious, being spread by direct person to person contact and through contaminated fomites. The infection is usually self-limiting in immunocompetent patients and often more widespread in those with atopic dermatitis and immunocompromising conditions such as HIV or AIDs. The lesions usually resolve on their own within 6 to 12 months but can also take years to completely disappear. There is no consensus in treatment guidelines for the management of molluscum contagiosum. Patients have been treated with curettage, cryodestruction with liquid nitrogen, electrodesiccation and chemical agents that include podophyllin, tretinoin, cantharidin, trichloroacetic acid, liquefied phenol, silver nitrate, tincture of iodine, or potassium hydroxide with cryotherapy, curettage, and cantharidin having the most support for use. Ycanth was the first FDA approved cantharidin product for the treatment of MC; it is indicated for use in adults and pediatric patients 2 years of age and older with MC, and is formulated as a drug-device combination that is administered by a healthcare provider.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Zelsuvmi was evaluated in 3 multicenter, randomized, double-blind, parallel-group, vehicle-controlled trials in subjects with MC (Trials 1, 2, and 3). Trial 1 (pivotal study) enrolled 891 subjects, Trial 2 enrolled 355 subjects, and Trial 3 enrolled 352 subjects. Subjects were randomized 1:1 in Trial 1, and 2:1 in Trials 2 and 3 to receive Zelsuvmi or vehicle applied to MC lesions once daily for up to 12 weeks. In the three trials, 3% of subjects were less than 2 years of age and 96% of subjects were 2 to 17 years of age. The primary efficacy endpoint was the proportion of subjects achieving complete clearance at Week 12. Complete clearance was defined as the subject having a total MC lesion count of 0 at assessment. The key secondary efficacy endpoint was complete clearance rate at Week 8. In trial 1 (B-SIMPLE4), 32.4% of patients experienced complete clearance with Zelsuvmi versus 19.7% with vehicle at week 12 (treatment difference of 12.7%; [$P < 0.001$]). In trial 2, 30.0% of patients experienced complete clearance at Week 12 with Zelsuvmi versus 20.3% with vehicle (treatment difference of 9.2%; 95% confidence interval [-0.04%, 18.4%]). Although the primary endpoint did not meet statistical significance in trial 2, statistical significance was met for the secondary endpoint with 13.9% of Zelsuvmi patients experiencing complete clearance at Week 8 versus 5.9% with vehicle (treatment difference of 7.8%; 95% confidence interval [1.8%, 13.8%]). In Trial 3, the primary endpoint at week 12 did not meet statistical significance with 26% of patients experiencing complete clearance with Zelsuvmi versus 22% with vehicle (95% confidence interval [-5%, 14%]).

References

1. Zelsuvmi [package insert]. LNHC, Inc. Durham, North Carolina. Updated July 2025.
2. Zelsuvmi New Drug Review. IPD Analytics. February 2024.
3. Zelsuvmi Drug Evaluation. Express Scripts. January 2024.
4. Browning JC, Enloe C, 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.* 022;158(8):871-878.
5. Ycanth topical solution [prescribing information]. West Chester, PA: Verrica; July 2023.

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12/04/2025 Medical Policy Committee review

12/10/2025 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 12/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.