

## PHARMACY COVERAGE GUIDELINE

### ZELSUVMI™ (berdazimer) topical gel Generic Equivalent (if available)

---

#### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

#### **Scope**

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

#### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
  - This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
  - Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
  - The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
  - The “Description” section describes the Service.
  - The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
  - The “Resources” section lists the information and materials we considered in developing this PCG
  - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
  - Information about medications that require prior authorization is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).
- 

## Medical Necessity Requirements for ZELSUVMI (berdazimer) topical gel

---

### Criteria for Initial Therapy:

#### **Prescriber Qualifications**

- Prescribed by a physician specializing in the diagnosis or in consultation with a Dermatologist

#### **Indication**

- Diagnosis of molluscum contagiosum

#### **Age Requirement**

- 1 year of age or older

ORIGINAL EFFECTIVE DATE: 08/21/2025 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE:

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

## PHARMACY COVERAGE GUIDELINE

### ZELSUVMI™ (berdazimer) topical gel Generic Equivalent (if available)

---

#### Baseline Clinical Evaluation

- At least 3 treatable lesions that are active (palpable, dome shaped, raised, pearly, shiny white top center) that are at least 2 cm away from the ocular region
- Will not be used to treat beginning of the end (BOTE) inflammatory reaction of MC

#### Alternative Therapies

- Failure (trial for at least three months duration), contraindication, intolerance to **TWO** of the following:
  - Cryotherapy
  - Curettage
  - Podofilox gel or solution (used off label)

#### Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Documentation Requirements

- A completed request form must be submitted, including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

#### Approval Duration:

- Up to 12 week
- 

#### Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
  2. Off-Label Use of Cancer Medications
- 

#### Description:

ZELSUVMI (berdazimer) topical gel is a nitric oxide (NO) releasing agent indicated for the topical treatment of molluscum contagiosum (MC) in adults and pediatric individuals 1 year of age and older.

Molluscum contagiosum (MC) is a common skin disorder that affects mainly healthy children. MC is a highly contagious viral skin infection caused by the molluscipoxvirus. It infects only the skin and, rarely, mucous membranes. MC is transmitted between human hosts by the infectious matter discharged from the lesions. MC is

ORIGINAL EFFECTIVE DATE: 08/21/2025 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE:

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

## PHARMACY COVERAGE GUIDELINE

### ZELSUVMI™ (berdazimer) topical gel Generic Equivalent (if available)

---

characterized by small, discrete, waxy, skin-colored, dome-shaped raised papules, averaging 3–5 mm in diameter. The papules may be umbilicated (small central depression or pit resembling a navel) and contain a caseous (cheese-like) plug. When the lesions are squeezed or traumatized, a creamy, grey-white material can be squeezed out. Lesions may be widespread, affecting sensitive body areas, causing pain, irritation, and redness. Individuals are prone to autoinoculation by scratching or rubbing. Most common areas of involvement include the trunk, axillae, antecubital and popliteal fossae, and crural folds. MC lesions are self-resolving. Treatment of lesions may be used to limit the spread to other sites and to other people. Lesions spontaneously resolve without scarring after approximately two months. In most cases, the infection is completely resolved in 6 to 12 months but sometimes it can persist for up to 5 years. Inflammatory reactions around MC lesions have been associated with imminent resolution of MC (sometimes referred to as “beginning-of-the-end” [“BOTE”] sign). BOTE may be associated with itching, but not pain.

When a trial of treatment is required, cryotherapy, curettage, cantharidin, or podophyllotoxin may be recommended over other therapies. Imiquimod, potassium hydroxide (KOH), salicylic acid, and topical retinoids have also been used for the treatment of MC. However, data in support of the efficacy of these treatments is insufficient for a recommendation for the routine use of these therapies.

Ycanth (cantharidin) is the only other Food and Drug Administration (FDA) approved treatment for MC in adult and pediatric individuals 2 years of age and older. It is administered by a healthcare provider.

---

#### **Definitions:**

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

---

#### **Resources:**

Zelsuvmi (berdazimer) topical gel product information, revised by LNHC, Inc. 01-2024. Available at DailyMed  
<http://dailymed.nlm.nih.gov>. Accessed June 21, 2025.

Isaacs SN. Molluscum contagiosum. In: UpToDate, Hirsch MS, Levy ML, Rosen T, Ofori AO. (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through May 2025. Topic last updated on May 30, 2025. Accessed June 21, 2025.

Browning JC, Enlow 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. Available at JAMA Dermatol. 2022;158(8):871-878. doi:10.1001/jamadermatol.2022.2721. Accessed June 21, 2025

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT03927703: A Phase 3 Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy and Safety of SB206 and Vehicle Gel Once Daily in the Treatment of Molluscum Contagiosum. Available from: <http://clinicaltrials.gov>. Last update posted March 23, 2023. Last verified March 2023. Accessed June 21, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT03927716: A Phase 3 Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy and Safety of SB206 and Vehicle Gel Once Daily in the Treatment of Molluscum Contagiosum. Available from: <http://clinicaltrials.gov>. Last update posted December 27, 2022. Last verified December 2022. Accessed June 21, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT04535531: A Phase 3 Multi-Center, Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Study Comparing the Efficacy and Safety of SB206 and Vehicle Gel Once Daily in the

ORIGINAL EFFECTIVE DATE: 08/21/2025 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE:

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.



An Independent Licensee of the Blue Cross Blue Shield Association

## PHARMACY COVERAGE GUIDELINE

### ZELSUVMI™ (berdazimer) topical gel Generic Equivalent (if available)

---

Treatment of Molluscum Contagiosum. Available from: <http://clinicaltrials.gov>. Last update posted January 26, 2023. Last verified November 2022. Accessed June 21, 2025.

ORIGINAL EFFECTIVE DATE: 08/21/2025 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE:

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.