Zelsuvmi (berdazimer) Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
10-01-2024	10-01-2024

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Zelsuvmi™ (berdazimer) Topical gel	Topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Molluscum contagiosum	Molluscum contagiosum is a viral skin infection caused by a poxvirus from the Poxviridae family. The virus is highly contagious and spreads through direct skin-to-skin contact or contact with contaminated objects or fomites. Since the virus lives only in the top layer of skin, once the lesions are gone the virus is gone and you cannot spread it to others. Infected individuals develop small, raised, flesh-colored bumps or lesions (Mollusca) on the skin, often with a central dimple containing a cheese like material (the virus). In most people, the lesions range from the size of a pinhead to as large as a pencil eraser (2 to 5 millimeters in diameter). They may become itchy, sore, red, and/or swollen and appear anywhere on the body except the palms and soles. The most common areas of involvement include the trunk, axillae, antecubital and popliteal fossae, and crural folds. Oral mucosal involvement is rare. Sexually transmitted molluscum contagiosum typically involves the groin, genitals, proximal thighs, and lower abdomen. While generally harmless and self-limiting, molluscum contagiosum typically resolves without scarring but may persist for 6-12 months or possibly as long as 4 years. It commonly affects children but can occur in individuals of any age and immunocompromised adults.(2,3,6) In the majority of patients, molluscum contagiosum resolves without any residual scars. Recurrences occur in one-third of patients.(5) According to American Academy of Dermatology Association guidelines, treatment may be recommended for patients who have: • A chronic skin condition, such as eczema • Molluscum in the genital area • A weakened immune system and numerous bumps

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	• Extremely bothersome molluscum Treatment options for MC include topical medications, cryotherapy, or minor procedures to remove the lesions. First line treatments include cantharidin and cryosurgery. Cantharidin is found in all body fluids of blister beetles, belonging to the order of Coleoptera and the family of Meloidae. There are currently more than 1500 species of cantharidin-producing beetles. The blister beetle solution, or cantharidin, is applied to the lesions and a blister forms destroying the virus as the body self heals.(3,4) Cantharidin is available as Ycanth and is applied by a dermatologist. Other chemical methods reported are: potassium hydroxide, podophyllotoxin, trichloroacetic acid, salicylic acid, lactic acid, glycolic acid, benzoyl peroxide, and tretinoin. Cryosurgery is liquid nitrogen applied topically by a dermatologist. The extreme cold "freezes" the virus and destroys the lesions but can also damage healthy skin. Because new molluscum lesions can form, retreatment may be needed every 2 to 3 weeks until the lesions are resolved. Cryosurgery can be painful and is therefore not recommended for young children or patients with a large amount of molluscum lesions.(2,3,5,6) Another treatment, curettage is when a dermatologist uses a medical device called a curette to remove the molluscum bumps from the skin. In skilled hands, this is an effective treatment that causes little or no bleeding. Because a dermatologist cuts into the skin, this treatment is not recommended for young children. Curettage is usually only performed on older children, teens, and adults.(3) Pulsed dye laser (PDL) may be a treatment option for someone who has many molluscum bumps. It's also recommended for patients with difficult-to-treat molluscum, including those who are immunosuppressed. Studies show that PDL can effectively treat dozens of bumps. During one such study, 43 patients who had many molluscum bumps were treated with the PDL. In 42 of these patients, all the bumps cleared within one month of PDL treatment. The treated skin tends to heal completely in 1 to 2 weeks on the face. When treating other areas of the body, the skin tends to heal completely in 2 to 4 weeks.(3) Treatment is recommended for people who have HIV and molluscum. In patients with HIV or those who are immunocompromised, the lesions are generalized and can grow big over large areas of skin when the CD4 counts are low. In these patients, spontaneous resolution of the lesions is rare.(5) Antiretroviral therapy (ART) is considered the treatment of choice for anyone who has HIV and has become infected with molluscum.(3) Cidofovir, an antiviral drug initially used in cytomegalovirus retinitis in HIV patients can be used topically at a concentration of 1–3% or intravenously. However, when used intravenously, it can cause nephrotoxicity.(6)
Efficacy	Zelsuvmi is is supplied as a 10.3% topical gel. It is supplied as two tubes, tube A contains berdazimer gel and tube B contains hydrogel. Each tube expires after 60 days of opening. The patient uses a dosing guide and measures out an equal amount from each tube using this dosing guide. After the 2 amounts are mixed together, the product is applied to the mollusca lesions every day for 12 weeks.(1) The efficacy of Zelsuvmi was evaluated in 3 multicenter, randomized, double-blind, parallel- group, vehicle-controlled trials in subjects with molluscum contagiousum (MC) (Trials 1, 2, and 3; NCT04535531, NCT03927703, and NCT03927716, respectively). Trial 1 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. Subjects had 3-70 baseline MC lesions. At baseline, the average MC lesion count was 20.2. 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 3, the complete clearance rates at Week 12 were 26% versus 22% for Zelsuvmi and vehicle, respectively, with 95% confidence interval (-5%, 14%).(1)

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Safety	Zelsuvmi does not have any contraindications.(1)

REFERENCES

Number	Reference
1	Zelsuvmi prescribing information. EPIH SPV, LLC. January 2024.
2	Oganesyan A, Sivesind TE, Dellavalle R. From the Cochrane Library: Interventions for Cutaneous Molluscum Contagiosum. JMIR Dermatol. 2023;6:e41514. Published 2023 Apr 25. doi:10.2196/41514
3	Molluscum contagiosum: Overview. https://www.aad.org/public/diseases/a-z/molluscum-contagiosum-overview.
4	Moed L, Shwayder T, Chang MW. Cantharidin revisited. Archives of Dermatology. 2001;137(10). doi:10.1001/archderm.137.10.1357.
5	Badri T, Gandhi GR. Molluscum Contagiosum. [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441898/.
6	Meza-Romero R, Navarrete-Dechent C, Downey C. Molluscum contagiosum: an update and review of new perspectives in etiology, diagnosis, and treatment. Clin Cosmet Investig Dermatol. 2019;12:373-381 https://doi.org/10.2147/CCID.S187224.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Zelsuvmi gel	TBD		M ; N ; O ; Y	Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Zelsuvmi gel	TBD		2	Kits	84	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zelsuvmi gel	TBD		FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zelsuvmi gel	TBD		FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. The patient has a diagnosis of molluscum contagiosum (MC) **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a conventional therapy (e.g., cantharidin, cryotherapy, curettage, podofilox) **OR** B. The patient has an intolerance or hypersensitivity to a conventional therapy **OR** C. The patient has an FDA labeled contraindication to ALL conventional therapy **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that conventional therapies are not recommended for the patient or cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient will NOT be using the requested agent in combination with another conventional therapy (e.g., cantharidin, cryotherapy, curettage, podofilox) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 weeks NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND BOTH of the following: A. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** B. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 weeks

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