

Molluscum Contagiosum: Persistent Burden, Unmet Need, and a Mechanism–Treatment Mismatch Despite Recent Therapeutic Advances

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Background:

Molluscum contagiosum (MC) is a contagious poxvirus infection caused by molluscum contagiosum virus (MCV; genus *Molluscipoxvirus*). A CDC-authored study reported a historical annual U.S. outpatient visit rate of ~22 per 10,000 persons;¹ with most cases not reaching medical attention, true incidence is considerably higher.² MC predominantly affects children aged 1–10 years. In 2023–2024, cantharidin 0.7% (YCANTH) and berdazimer gel 10.3% (Zelsuvmi) received FDA approval as the first dedicated MC therapies. Despite these advances, many cases remain untreated, and the clinical and psychosocial burden persists.³ Less attention has been paid to how mechanistic limitations of available therapies may themselves shape observed epidemiology and care-seeking behavior.

Objectives:

To characterize the persistent unmet need and clinical, psychosocial, and behavioral burden of MC despite recent FDA approvals; evaluate the alignment of current therapies with viral pathophysiology; and examine how therapeutic limitations may shape patient care-seeking.

Methods:

A targeted review was conducted of epidemiologic data, patient-reported outcomes, and pivotal phase 3 trials of cantharidin 0.7% and berdazimer gel 10.3%.^{4,5,6} Outcomes were evaluated alongside mechanism of action, tolerability, and mode of administration. Therapeutic inflection points in onychomycosis and herpes zoster were referenced as comparators.

Results:

MC lesions may persist for 8–18 months or longer, with patient-reported durations of up to 2 years in trial populations.^{3,6,9} Household transmission rates approach 41%, extending burden across siblings and caregivers.⁹ Visible, exposed-area lesions contribute to self-consciousness, activity restriction, and social exclusion in affected children.⁶ Cantharidin demonstrated complete clearance in 46–54% of patients in phase 3 trials but produced local skin reactions in ~97% and required in-office administration across multiple visits.⁴ Berdazimer gel enables at-home application but achieved complete clearance in roughly one-third of patients at 12 weeks.⁵

Mechanistically, MCV replicates exclusively within keratinocytes and employs immune-evasion strategies that limit host clearance.¹² Cantharidin is a vesicant, and berdazimer is a nitric oxide-releasing agent whose mechanism of action in treating MC is unknown.¹³ Neither therapy has demonstrated direct, clinically confirmed antiviral activity against MCV.

In a 2009 U.S. survey, 41.6% of healthcare providers selected reassurance that molluscum contagiosum would resolve when asked what advice they would give patients.⁷ For comparison, in onychomycosis, where approximately half of affected patients historically failed to seek medical advice,⁸ oral terbinafine offered improved cure rates and tolerability, repositioning the condition from one largely tolerated without intervention to one actively managed. Analogous inflection points following effective herpes zoster and herpes labialis therapies suggest that observed MC epidemiology may partially reflect treatment-driven care avoidance rather than true disease infrequency.



Conclusion:

Despite recent FDA approvals, MC continues to carry substantial clinical and psychosocial burden. Current therapies do not consistently achieve complete lesion clearance or meet patient and caregiver needs for tolerability and convenience. The resulting mechanism–treatment mismatch may function not only as a clinical limitation but as a driver of suppressed care-seeking. Therapies that are both directly antiviral and meaningfully better tolerated may improve clinical outcomes and expand appropriate treatment engagement within a large, underserved patient population.

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²McCollum AM, Holman RC, Hughes CM, et al. Molluscum contagiosum in a pediatric American Indian population: incidence and risk factors. *PLoS One*. 2014;9(7):e103419.

³Centers for Disease Control and Prevention. Clinical Overview of Molluscum Contagiosum. Updated April 15, 2025. Accessed May 6, 2025. <https://www.cdc.gov/molluscum-contagiosum/hcp/clinical-overview/index.html>.

⁴Eichenfield LF, McFadden W, Brabec B, et al. Safety and efficacy of YP-102, a proprietary drug-device combination product containing cantharidin, 0.7% (w/v), in children and adults with molluscum contagiosum: two phase 3 randomized clinical trials. *JAMA Dermatol*. 2020;156(12):1315-1323.

⁵Browning JC, Enloe G, 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.

⁶Browning JC, Cartwright M, Thoria L, et al. A patient-centered perspective of molluscum contagiosum as reported by B-SIMPLE4 clinical trial patients and caregivers: global impression of change and exit interview substudy results. *Am J Clin Dermatol*. 2023;24(1):119-133.

⁷Hughes CM, Damon IK, Reynolds MG. Understanding U.S. healthcare providers' practices and experiences with molluscum contagiosum. *PLoS One*. 2013;8(10):e76948.

⁸Roberts DJ. Onychomycosis: current treatment and future challenges. *Br J Dermatol*. 1999;141(5):601-4.

⁹Olsen JR, Gallacher J, Finlay AV, Piquet Y, Francis NA. Time to resolution and effect on quality of life of molluscum contagiosum in children in the UK: a prospective community cohort study. *Lancet Infect Dis*. 2015;15(2):190-195.

¹⁰U.S. Food and Drug Administration. YCANTH (cantharidin) topical solution, 0.7%. Prescribing Information. 2023. Accessed August 11, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212905s000lbl.pdf.

¹¹U.S. Food and Drug Administration. NDA/BLA Multi-Disciplinary Review and Evaluation, NDA 217424-ZELSUVMI (berdazimer sodium gel). Review completion date: January 4, 2024. Accessed August 11, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217424Orig1s000MultidisciplineR.pdf.

¹²Yoon K, Smythe C, Yousefi F, Berman B. Molluscum contagiosum virus evasion of immune surveillance: a review. *J Drugs Dermatol*. 2022;22(2):182-189. doi:10.36849/JDD.27230.

¹³U.S. Food and Drug Administration. ZELSUVMI (berdazimer) topical gel, 10.3%. Prescribing Information. 2024. Accessed August 11, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217424s000lbl.pdf.



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