Need for a tolerable and efficacious topical Molluscum Contagiosum drug for pediatric use

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Objectives:

To evaluate the current treatment landscape for molluscum contagiosum (MC) in pediatric patients and identify remaining therapeutic gaps despite recent FDA drug approvals.

Method:

A literature review was conducted examining MC epidemiology, current FDA-approved treatments, and their clinical trial data. Published prescribing information and FDA multi-disciplinary reviews for topical cantharidin 0.7% (TC) and topical berdazimer gel 10.3% (TBG) were analyzed for efficacy, tolerability, and administration requirements.

Results:

MC is most prevalent in pediatrics, with some estimates placing the prevalence of MC in children aged 0-16 between 5.1% and 11.5%.[2] Traditional treatments have been cryotherapy, laser therapy, and curettage, each being painful, skin-destructive, has the potential to scar, and is inconvenient to administer. Additionally, there are two newly FDA-approved topical drugs: topical cantharidin 0.7% (TC) and topical berdazimer gel 10.3% (TBG), with Phase 3 trial results reported below. Both present significant limitations. TC relies on application site blistering with accompanying pain and scarring, and requires two-part mixing and must be applied in a healthcare practitioner's office.[3] TBG, while somewhat more tolerable, also has significant side effects and patient tolerability problems, is considerably less efficacious than TC, and requires two-part mixing just prior to use by the patient or caregiver.[4]

Table 1: TC Pivotal Trials Patients with Moderate to Severe Application Site Adverse Events

	TC (n = 311)		Vehicle (n = 216)	
	Moderate	Severe	Moderate	Severe
Vesicles	32%	4%	2%	0%
Pain	20%	2%	16%	1%
Pruritus	8%	1%	7%	0%
Scab	9%	0%	1%	0%
Erythema	21%	<1%	7%	0%
Discoloration	4%	<1%	1%	0%
Dryness	2%	0%	1%	0%
Edema	3%	0%	1%	0%
Dermatitis	1%	0%	0%	0%

Source: FDA-Approved Prescribing Information for Ycanth[3]

Table 2: TBG Pooled Phase 3 Trials with an Occurrence of 1% or greater Adverse Events

	Active (n = 916)	Vehicle (n = 680)
Pain	18.7%	4.9%
Erythema	11.7%	1.3%
Pruritus	5.7%	1.0%
Exfoliation	5.0%	0.0%
Dermatitis	4.9%	0.7%
Scar	4.0%	6.9%
Swelling	3.5%	0.6%
Erosion	1.6%	0.1%
Discoloration	1.5%	0.1%
Vesicles	1.5%	0.1%
Irritation	1.2%	0.0%

Source: FDA Multi-Discipline Review of Zelsuvmi[4]

"The ideal pediatric MC treatment, safe, well-tolerated, efficacious, and easy to administer, remains an unmet medical need despite recent FDA approvals.

Watchful waiting remains common, not because it is ideal, but because available treatments are painful, poorly tolerated, or inconvenient.

The therapeutic gap is real."

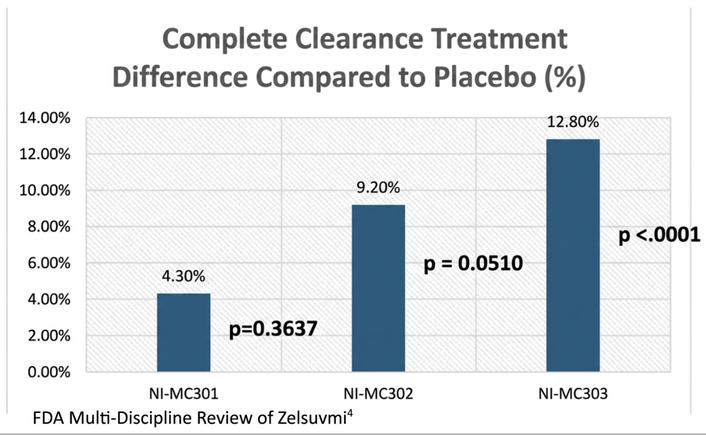
Richard Panico, MBA, Precefi, Inc.

Table 3: TC and TBG Complete Clearance Rate of MC Lesions at Weeks 12

	TC (VP-102-102)			TBG (NI-MC304)		
	Active n = 160	Vehicle = 106	% Difference	Active n = 444	Vehicle n = 447	% Difference
12 Week	53.7%	13.3%	40.4%	30.0%	19.8%	10.2%

Source: FDA Multi-Discipline Review of Ycanth[5], FDA Multi-Discipline Review of Zelsuvmi[4]
Note: For both TC and TBG, the pivotal trial with the largest treatment difference was chosen for comparison, as no reliable pooled data for TBG were available in the FDA's review.

Table 4: TBG Pivotal Trials Complete Clearance Treatment Difference Compared to Vehicle



FDA Multi-Discipline Review of Zelsuvmi[4]

Discussion:

A substantial unmet need remains for an effective, safe, well-tolerated, pain and scar-free, easy-to-use treatment of molluscum contagiosum.[1,2,5]

Despite recent regulatory approvals, a meaningful therapeutic gap persists in pediatric MC treatment.[1] Current therapies are limited by factors including application site reactions, tolerability problems, and logistical challenges related to administration.

The ideal treatment would combine high efficacy with excellent tolerability and convenient administration. Until such a treatment becomes available, MC will likely continue to be managed with either painful and destructive therapies with potential for scarring or watchful waiting.

A topical therapy that is efficacious, safe, well-tolerated, scar-free, and easy to administer has the potential to represent a significant advancement for a large pediatric patient population still in need.

Zabalafin hydrogel, an investigational topical antiviral therapeutic from a first-of-its-kind all-natural drug platform, has demonstrated promising early clinical results and may represent a potential, efficacious, safe, well-tolerated, and non-scaring, easy-to- use drug to address this significant gap in MC treatment.

[1] Hebert AA, Bhatia N, Del Rosso JQ. Molluscum Contagiosum: Epidemiology, Considerations, Treatment Options, and Therapeutic Gaps. J Clin Aesthet Dermatol. 2023;16(8 Suppl 1):S4-S11. PMID: 37636018; PMCID: PMC10453394.
[2] Olsen JR, Gallacher J, Piguet V, Francis NA. Epidemiology of molluscum contagiosum in children: a systematic review. Fam Pract. 2014;31(2):130-136. doi:10.1093/fampra/cmt075. (Note: Publication year is 2014 in print, epub 2013.)
[3] YCANTH (cantharidin) topical solution [prescribing information]. Verrica Pharmaceuticals Inc; 2023. Accessed January 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212905s000lbl.pdf.
[4] U.S. Food and Drug Administration. Multi-Discipline Review: ZELSUVMI (berdazimer) topical gel, NDA 217424. January 2024. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/217424Orig1s000MultidisciplineR.pdf.
[5] U.S. Food and Drug Administration. Multi-Discipline Review: YCANTH (cantharidin) topical solution, NDA 212905. 2023. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/212905Orig1s000MultidisciplineR.pdf.