# Clinical Limitations of FDA-Approved Topical Therapies for Pediatric Molluscum Contagiosum

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## SYNOPSIS

Currently, two topical drugs are FDA-approved for the treatment of MC: cantharidin (TC) and berdazimer gel (TBG). TC was the first FDA-approved treatment for MC. It must be applied by the healthcare practitioner (HP) in the HP's office, which is inconvenient for the patient and time-consuming for the HCP. The application is often very painful, with widespread redness, itching, pain, and blistering.[1] TC efficacy in the treatment of MC was compared with placebo, with 40.9% and 49.6% of children receiving TC achieving complete clearance at Day 84 in the pivotal clinical trials VP-102-101 and VP-102-102, respectively.[2] TBG is applied at home daily and is somewhat better tolerated than TC, but has a significant percentage of users reporting pain plus other side effects. Complete clearance with TBG is less frequent than TC, and the most positive Phase 3 trial showed a 32.4% complete clearance at 12 weeks.[3] Neither of these drugs provides a safe, gentle remedy for MC, but rather have a high adverse event burden, poor patient tolerability, and are not preferred by clinicians or patients.

Sales uptake of TC has been slow, especially given the reported 8 million US MC patient population.[4] Sourcing TC can be an issue. In Q2 of 2025, only 13,434 TC single-use applicators were shipped.[5] Patients often require multiple application treatments, meaning true patient use is likely smaller. TBG, launched in July 2025, has had better-than-expected growth.[6] A serious problem for TGB is that the active drug product must be mixed with its carrier by the patient/caregiver in the home and is single use. Given the reported size of the US MC patient population, the amount of FDA-approved MC drug prescriptions is quite small.

Contrary to what is often stated, MC is not completely benign. While it is self-limiting and rarely life-threatening in a healthy pediatric patient, 10% of MC patients develop molluscum dermatitis.[4] In patients with preexisting atopic dermatitis (AD), MC often has a more severe presentation and worsens the existing AD.[4] As long as MC lesions are present, the MC sufferer remains contagious. So, unless 100% clearance is achieved, MC can be passed to family members and others. To truly provide an effective therapeutic for MC and to blunt community spread, a new drug is needed that can readily produce complete clearance while being safe, gentle, and pain-free.

## OBJECTIVE

To review the epidemiologic data for pediatric MC and critically assess the clinical performance and practical use considerations of FDA-approved topical therapies in pediatric populations.

## METHODS

Published literature describing the epidemiology of pediatric MC was reviewed alongside publicly available clinical trial data, prescribing information, and FDA multidisciplinary review documents for topical cantharidin 0.7% and topical berdazimer gel 10.3%. Evaluation focused on treatment efficacy, safety, and tolerability profiles, and administration requirements relevant to pediatric dermatology practice. The data were used to create the tables below. The selection of which data to present was the decision of Precefi; none of these tables were pulled verbatim from FDA materials, and they do not represent the FDA's views.

## DISCUSSION

Although recent FDA approvals represent progress in the treatment of pediatric MC, current topical therapies do not address the combined need for a safe, gentle, pain-free, effective treatment. The unmet need for a pediatric, clinician- and caregiver-desirable MC drug remains significant.[7,8]

As shown in the tables above, TC and TBG produce significant adverse events. TC is far worse than TBG in this regard. Reactions of moderate severity to TC often eclipse all AEs of the same term for TBG. While TBG may be more tolerable, 12 weeks of daily application yield a complete clearance rate that is only 12.8% better than placebo. Analyzing TGB's Phase 3 studies, the outcomes are even worse: neither of the pivotal studies reached statistical significance.[3]

The wholesale acquisition prices of TC and TBG are $685 per applicator[9] and $1,950[10] a month, respectively. Using the same 12-week endpoints as in the clinical trials for both, this would yield wholesale costs of $2,470 for TC (assuming 4 applications, one every 3 weeks) and $5,850 for TBG. However, significant side effects, poor patient tolerability, and low efficacy diminish the impact of their high insurance or third-party payer reimbursement.

As a result, clinicians and families must continue to balance treatment-related pain and discomfort, logistical considerations, with the option of observation with no treatment. Additional therapeutic options with improved efficacy, safety, and tolerability profiles, and simplified administration would enhance treatment acceptance and outcomes in pediatric MC patients.

**Table 1:** Patients With Moderate or Severe Application Site Adverse Events in Pivotal TC Trials

| | 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[2]

**Table 2:** Adverse Events from Pooled Phase 3 Trials With an Occurrence of 1% or Greater

| | 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% |

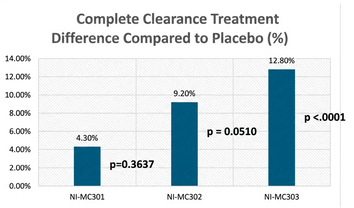
Source: FDA Multi-Discipline Review of Zelsuvmi[3]

**Table 3:** Complete Clearance Rate of MC Lesions at Weeks 8 and 12, TC and TBG

| | 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% | 32.4% | 19.7% | 12.8% |

Source: FDA Multi-Discipline Review of Ycanth[2], FDA Multi-Discipline Review of Zelsuvmi[3]
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:** Complete Clearance Treatment Difference Compared to Placebo, or TBG Pivotal Trials





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