Ycanth (cantharidin)
PAM – 088

Iowa Medicaid Program	Prior Authorization	**Effective Date**	01/01/2024
Revision Number	1	**Last Reviewed**	10/18/2024
Reviewed By	Medicaid Medical Director	**Next Review**	10/17/2025
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	10/18/2024

Overview

Medication: [1]	cantharidin
Brand Name:	Ycanth™
Pharmacologic Category:	Dermatological agents, miscellaneous
FDA-Approved Indication(s):	Topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older
How Supplied:	• Glass ampule contained within a single-use applicator. Each ampule contains approximately 0.45 mL of a 0.7% cantharidin solution (7 mg cantharidin per 1 mL [0.7%]). • A Ycanth Break Tool is co-packaged as 2 units per each carton of applicators (supplied as either 6 or 12 applicators per carton).

Dosage:

- Apply topically as a single application to cover each lesion. Remove with soap and water 24 hours later.
- Use no more than two applicators during a single treatment session.
- Administer every 3 weeks as needed.

Administration:

- All healthcare professionals should receive instruction and training prior to preparation and administration.
- For topical use only. Not for oral, mucosal, or ophthalmic use. Avoid contact with the treatment area, including oral contact, after Ycanth™ treatment. Do not apply near the eyes.
- Use nitrile or vinyl gloves and eye protection during preparation and administration.
- If severe blistering, severe pain, or other severe adverse reactions occur, remove Ycanth™ with soap and water prior to 24 hours after treatment.
- Apply a small droplet onto a molluscum lesion and use the applicator tip to spread the solution to cover the entire lesion.
- Repeat the application until all lesions have been treated.
- Allow solution to completely dry (up to 5 minutes) before contacting healthy skin to avoid transference.
- Do not cover any treated lesions with bandages.

Benefit Category:	Medical

Descriptive Narrative

Molluscum contagiosum is characterized by clusters of pink, dome-shaped, smooth, waxy, or pearly and umbilicated papules 2 to 5 mm in diameter caused by molluscum contagiosum virus, a poxvirus. Diagnosis is based on clinical appearance (skin biopsy or smear of expressed material shows characteristic inclusion bodies but is necessary only when diagnosis is uncertain). Most lesions spontaneously regress in 1 to 2 years, but they may remain for 2 to 3 years.

Treatment is indicated for cosmetic reasons or for prevention of spread, and may include:

- Physical removal: curettage, cryosurgery, laser therapy, or electrocautery;
- Topical irritants (e.g., trichloroacetic acid, cantharidin, tretinoin, tazarotene, podofilox);
- Intralesional injection or photodynamic therapy;
- Combination therapies.[2]

Potential advantages of successful treatment include limitation of lesion spread to other sites, reduction in risk of transmission to others, resolution of pruritus when present, and prevention of scarring that can result from lesions that become inflamed, traumatized, or secondarily infected. Treatment may also reduce the patient, parent, or caregiver's psychologic stress over the appearance of lesions. However, depending on the chosen therapy, treatment can be time consuming or result in adverse effects such as pain, irritation, dyspigmentation, or scarring.[3]

Guidelines

Many children with molluscum contagiosum (MC) lesions are managed by pediatricians or primary care physicians who often elect to not treat MC, which may be due to the prevailing belief that the lesions will go away on their own ("benign neglect"). What is often not considered when deciding to take the noninterventional approach is that the average time to spontaneous resolution of MC is approximately 13 months, with 30 percent of the cases persisting for more than 18 months; additionally, around 40 percent of the cases will transmit the infection to other individuals in the household.[4]

The recently updated Red Book Atlas of Pediatric Infectious Diseases[5] states that therapy for MC "may be warranted to alleviate discomfort, including itching; reduce autoinoculation; limit transmission of the virus to close contacts and reduce cosmetic concerns and prevent secondary infections." This recognition that MC is highly contagious and spreads rapidly among children in contact with other children, not only through physical contact but

also likely via the sharing of toys, utensils, books, clothing, and other items, is clinically relevant. While MC in a healthy child is potentially self-limiting over time, there are additional reasons to treat them beyond persistence and potential spread to others, including prevention of molluscum dermatitis and adverse psychosocial sequelae, as well as exacerbation of atopic dermatitis. Many cases of MC are asymptomatic, but children might be troubled by pruritus, and the subsequent scratching of the MC papules can lead to further autoinoculation.[4]

Criteria

Prior authorization is required.

Ycanth™ is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of molluscum contagiosum; **AND**
2. Member meets **AT LEAST ONE** of the following:
    a. Member has severe symptoms of itching and pain associated with lesions; **AND/OR**
    b. Member is immunocompromised or has a concomitant bacterial infection or concomitant atopic dermatitis; **AND/OR**
    c. Infection is in an area where lesions cannot be reasonably covered and there is a concern for risk of spread to contacts (i.e., siblings, daycare); **AND**
3. Member is 2 years of age or older; **AND**
4. Documentation of **ONE** of the following (a **or** b):
    a. Member is treating new lesions that have not been previously treated with Ycanth™; **OR**
    b. Lesions have been previously treated with Ycanth™ and will not exceed a total of 4 treatments with Ycanth™; **AND**
5. Ycanth™ will not be used in combination with other treatment modalities for molluscum contagiosum (e.g., cryotherapy, curettage, podofilox, or Zelsuvmi®); **AND**
6. Medication will be applied by a healthcare provider who has received instruction and training in the preparation and administration of Ycanth™; **AND**
7. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Ycanth™ is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by a reduction in the size or number of lesions; **AND**
3. At least 3 weeks have passed since the previous application; **AND**
4. Total duration of therapy has not exceeded 4 applications; **AND**
5. Medication will be applied by a healthcare provider who has received instruction and training in the preparation and administration of Ycanth™; **AND**
6. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	6 months
Quantity Limits	Maximum of: • 2 applicators per treatment session • 8 applicators per 12 weeks • 12 weeks per year	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
~~C9164~~	~~Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)~~ – *effective 01/01/2024 to 03/31/2024*
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg) – *effective 04/01/2024*

ICD-10	Description
B08.1	Molluscum contagiosum

NDC (and strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
71349-0070-01 (single applicator, 3.2 mg)	Verrica Pharmaceuticals Inc. (71349)	1 app.	1	EA	1
71349-0070-06 (6 applicators/carton)	Verrica Pharmaceuticals Inc. (71349)	1 app.	6	EA	6
71349-0070-12 (12 applicators/carton)	Verrica Pharmaceuticals Inc. (71349)	1 app.	12	EA	12

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Ycanth™ prescribing information (07/2023). Verrica Pharmaceuticals Inc.: West Chester, PA. Available online: www.ycanthpro.com. Accessed June 24, 2024.

[2] Molluscum Contagiosum. *Merck Manual Professional Version – Online.* Reviewed/Revised June 2023. Available online: www.merckmanuals.com/professional. Accessed June 25, 2024.

[3] Isaacs SN. Molluscum contagiosum. Ofori AO, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed August 27, 2024.

[4] Hebert AA, Bhatia N, Del Rosso JQ. Molluscum Contagiosum: Epidemiology, Considerations, Treatment Options, and Therapeutic Gaps. J Clin Aesthet Dermatol. 2023 Aug;16(8 Suppl 1):S4-S11. PMID: 37636018

[5] Davies HH, Jackson MA, Rice SG. Molluscum contagiosum. In: Baker CJ (ed). Red Book Atlas of Pediatric Infectious Diseases, 4th ed. Washington, DC: American Academy of Pediatrics, 2019. pp. 435–437.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources

may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History			
Change Date	**Changed By**	**Description of Change**	**Version**
[mm/dd/yyyy]	CAC		[#]
Signature			

Change Date	**Changed By**	**Description of Change**	**Version**
[mm/dd/yyyy]	CAC		[#]
Signature			

Change Date	**Changed By**	**Description of Change**	**Version**
10/18/2024	CAC	Criteria implementation. Draft version included criterion requiring that Ycanth is prescribed by, or in consultation with, a dermatologist. Requirement removed per committee discussion and vote.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee