09-J4000-68

Original Effective Date: 11/15/23

Reviewed: 10/11/23

Revised: 04/01/24

Subject: Cantharidin (Ycanth)

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DESCRIPTION:

Molluscum contagiosum (MC) is a common viral infection that primarily affects children, immunocompromised individuals, and sexually active adults. It is caused by a poxvirus, and results in a benign, mild skin disease characterized by lesions that may appear anywhere on the body. Direct person-to-person physical contact and contact through contaminated fomites is results in the virus spreading. Additionally, MC can spread it to other parts of the body via touching or scratching a lesion and then touching another part of the body. MC typically resolves within 6–12 months but may take as long as 4 or 5 years.

Because MC is self-limiting in healthy individuals, treatment may be unnecessary. Issues such as lesion visibility, itching, pain, underlying atopic dermatitis (AD), concomitant bacterial infection, lesions located in the genital area, and the desire to prevent transmission may prompt the decision to initiate therapy. There are no widely recognized clinical guidelines or a consensus on the optimal treatment for MC. A large variety of treatments are available with varying levels of evidence. Choice of treatment is often based on patient-specific factors, such as need for an at-home therapy or to limit the risk of scarring. Treatment options include physical removal (cryotherapy, curettage, laser), topical therapy (compounded cantharidin, retinoids, potassium hydroxide, podophyllotoxin, imiquimod, salicylic acid), and oral therapy (cimetidine).

On July 21, 2023, the U.S. Food and Drug Administration (FDA) approved Verrica Pharmaceuticals' cantharidin preparation for the topical treatment of MC in adult and pediatric patients 2 years of age and older. Ycanth is the first FDA-approved medication for this condition. Ycanth is a drug-device product that delivers the topical solution via a single-use applicator and must be administered by a healthcare provider.

The safety and efficacy of Ycanth were evaluated in two identical phase 3, randomized, double-blind trials (CAMP-1 and CAMP-2). Participants were 2 years of age and older and diagnosed with MC. Participants were randomized by household to receive one of the following via topical administration to all baseline and new lesions once every 21 days until clear or for a maximum of 4 applications (on Days 1, 21, 42, and 63): Ycanth or vehicle (placebo). The primary endpoint was proportion of patients achieving complete clearance of all treated MC lesions at Day 84. Secondary endpoints were the proportion of patients achieving complete clearance of all treated MC lesions at Day 63, 42, and 21.

Both trials met the primary endpoint of complete clearance of all treatable MC lesions. In the combined study population, complete clearance of all MC lesions at Day 84 occurred in 50% of patients in the Ycanth group and in 15.6% of patients in the vehicle group (P <0.0001). Mean MC lesion counts decreased by 76% for patients in the Ycanth group and 0.3% for patients in the vehicle group at Day 84 (P <0.0001). Full study results are below:

Percentage of Subjects Exhibiting Complete Clearance of Treatable Molluscum Contagiosum Lesions in Trial 1 and Trial 2 (Intent-to-Treat Population)

	CAMP-1			**CAMP-2**		
	YCANTH N = 160	**Vehicle N = 106**	**Treatment Difference (95% CI)***	**YCANTH N = 150**	**Vehicle N = 112**	**Treatment Difference (95% CI)***
Day 84	46%	18%	29% (19%, 38%)	54%	13%	40% (30%, 51%)
Day 63	32%	17%	15% (4%, 25%)	28%	5%	23% (15%, 32%)
Day 42	21%	9%	10% (2%, 19%)	13%	4%	9% (3%, 16%)
Day 21	11%	4%	8% (2%, 14%)	5%	2%	3% (-1%, 8%)

*Treatment difference and 95% CI based on Generalized Estimating Equations (GEE) model for logistic regression with an exchangeable working correlation structure, a factor for treatment, and repeated measurements allowed for a household. Subjects with missing data are imputed as non-responders.

Adverse events (AEs) were seen in 99% (CAMP-1) and 95% (CAMP-2) of patients in the Ycanth group and 73% (CAMP-1) and 66% (CAMP-2) of patients in the placebo group. The most common AEs in the Ycanth group were application site blistering, pruritus, pain, and erythema, which were generally mild or moderate in severity.

POSITION STATEMENT:

Cantharidin (Ycanth) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Member is diagnosed with molluscum contagiosum (MC)
2. Member is experiencing itching or pain, has a concomitant bacterial infection, or has concomitant AD, or there is concern for contagion (e.g. other siblings, daycare) and lesions cannot be reasonably covered using a bandage
3. Cantharidin is prescribed and administered by a dermatologist (including nurse practitioners and physician assistants working in a dermatology practice)
4. Member meets one of the following:
    a. MC has not resolved one year after diagnosis, with or without conventional therapy – documentation from the medical record must be submitted
    b. MC is resulting in severe symptoms of itching or pain – documentation from the medical record must be submitted
5. Member's current lesions have not been treated with cantharidin in the past
6. Member is 2 years of age or older
7. Dose does not exceed 2 applicators per treatment every 3 weeks
8. Use will be limited to 4 treatment cycles per infection (max of 8 applicators for approval duration)

Approval duration: 6 months

DOSAGE/ADMINISTRATION:

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FDA-approved

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

Dose Adjustments

- None

Drug Availability

- Topical solution: 0.7% cantharidin

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warning-

- Toxicities Associated with Inappropriate Administration: Life-threatening or fatal toxicities can occur if administered orally. Avoid contact with the treatment area, including oral contact, after treatment. Ocular toxicity can occur if YCANTH comes in contact with eyes.
- Local Skin Reactions: Reactions at the application site have included vesiculation, pruritus, pain, discoloration, and erythema. Avoid application near eyes and mucosal tissue, and to healthy skin.
- Flammability: Avoid fire, flame or smoking near lesion(s) during treatment and after application until removed.

BILLING/CODING INFORMATION:

HCPCS Coding

J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)

ICD-10 Diagnosis Codes That Support Medical Necessity

B08.01	Molluscum contagiosum

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

1. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2023 [cited 10/1/23]. Available from: http://www.clinicalpharmacology.com/.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine; 2000 Feb 29 - [cited 10/1/23]. Available from: http://clinicaltrials.gov/.
3. DRUGDEX® System [Internet]. Greenwood Village (CO): Thomson Micromedex; Updated periodically [cited 10/1/23].
4. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2019 [cited 10/1/23]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.
5. Verrica. Ycanth (cantharidin). 2023 [cited 10/1/23]. In: DailyMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7c9bdeaa-9822-4c69-a719-ea4a8643f59c.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 10/11/23.

GUIDELINE UPDATE INFORMATION:

11/15/23	New Medical Coverage Guideline.
01/01/24	Revision: Added HCPCS code C9164.
02/15/24	Revision; Updated Position Statement.
04/01/24	Revision: Added HCPCS code J7354 and deleted codes C9164 and J3490.