LOUISIANA BLUE

cantharidin (Ycanth™)

Policy # 00875
Original Effective Date: 05/13/2024
Current Effective Date: 05/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider cantharidin (Ycanth™)‡ for the treatment of molluscum contagiosum to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for cantharidin (Ycanth) will be considered when the following criteria are met:

- Patient has a diagnosis of molluscum contagiosum; AND
- Patient is 2 years of age and older.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of cantharidin (Ycanth) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary**)** to be **investigational.***

Based on review of available data, the Company considers the use of cantharidin (Ycanth) for any non-FDA approved indication to be **investigational.***

Background/Overview

Ycanth is a cantharidin based topical solution indicated for the treatment of molluscum contagiosum in adults and pediatric patients 2 years of age and older. It is available as a glass ampule that contains 0.45 mL of 0.7% cantharidin solution with a single use applicator. Ycanth must be applied topically by a healthcare professional to each lesion once every 21 days as needed. Ycanth must be washed off with soap and water 24 hours after application.

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Molluscum contagiosum is a common viral skin infection caused by the Poxviridae family that causes white-, pink-, or flesh-colored bumps/lesions in groups or alone on any part of the body. It can occur at any age but is most common in younger ages. This condition is contagious, being spread by direct person to person contact and through contaminated fomites. The infection is usually self-limiting in immunocompetent patients and often more widespread in those with atopic dermatitis and immunocompromising conditions such as HIV or AIDs. The lesions usually resolve on their own within 6 to 12 months but can also take years to completely disappear. There is no consensus in treatment guidelines for the management of molluscum contagiosum. Patients have been treated with curettage, cryodestruction with liquid nitrogen, electrodesiccation and chemical agents that include podophyllin, tretinoin, cantharidin, trichloroacetic acid, liquefied phenol, silver nitrate, tincture of iodine, or potassium hydroxide with cryotherapy, curettage, and cantharidin having the most support for use. Prior to FDA approval of Ycanth, cantharidin was often compounded by pharmacies in various strengths in different vehicles. Ycanth is the first and only FDA approved cantharidin product.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Ycanth is indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Ycanth was evaluated in two identical Phase III, double-blind, vehicle controlled, multicenter studies. Eligible patients were healthy adults and children 2 years of age and older with a clinical diagnosis of molluscum contagiosum with treatable lesions. 528 patients were randomized by household in a 3:2 ratio to receive Ycanth or vehicle. Patients' lesions were treated with either Ycanth or vehicle at intervals of approximately 21 days until complete clearance of the lesion or for a maximum of 4 applications (on Days 1, 21, 42, and 63). Study drug solution was applied and left on the lesions for approximately 24 hours before the lesions were washed with soap and water. The primary efficacy endpoint was the proportion of the Ycanth treated patients achieving complete clearance of all molluscum contagiosum lesions compared to those who received the vehicle at Day 84 of the trial. For the first trial, 46% of patients had complete clearance of molluscum contagiosum lesions in the Ycanth arm compared with 18% of patients in the vehicle arm ($P < 0.001$). In the second trial, 54% of the Ycanth patients had complete clearance compared with 13% of patients given vehicle ($P < 0.001$).

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References

1. Ycanth [package insert]. Verrica Pharmaceuticals Inc. West Chester, Pennsylvania. Updated July 2023.
2. Ycanth Drug Evaluation. Express Scripts. Updated August 2023.
3. Ycanth (cantharidin). IPD Analytics. Updated September 2023.

Policy History

Original Effective Date: 05/13/2024
Current Effective Date: 05/01/2025
04/04/2024 Medical Policy Committee review
04/10/2024 Medical Policy Implementation Committee approval. New policy.
04/03/2025 Medical Policy Committee review
04/09/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J7354
ICD-10 Diagnosis	All Related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.