

Ycanth (cantharidin)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

Molluscum contagiosum (molluscum) is a widespread skin infection caused by the molluscum virus, a dermatotropic DNA poxvirus. This condition predominantly affects children and is common worldwide. The infection results in small, flesh-colored papules and papulovesicles, measuring 1-4 mm across, which

usually have a distinct umbilicated or dimpled center. These papules are typically not accompanied by much inflammation; however, when an inflammatory response is observed, it often signals the start of disease resolution.

- Although molluscum lesions are generally painless, they might itch or become irritated. Scratching or picking at the bumps can lead to autoinoculation, scarring, or secondary bacterial infections.
- The primary mode of molluscum transmission is through direct person-to-person contact or by autoinoculation. Indirect transmission can occur through touching contaminated items like towels, clothes, or toys.
- In immunocompetent individuals, molluscum contagiosum often resolves spontaneously within 6 to 12 months. Treatment may be warranted to decrease spread, relieve symptoms, or reduce duration.
- It is generally recommended that adolescents and adults with sexually transmitted cases of molluscum contagiosum be treated to reduce the spread of the disease to others, including those who may be immunocompromised.
- Immunocompromised individuals are at a higher risk of extensive and persistent disease, and thus commonly treated to prevent a severe infection.

Molluscum contagiosum is often self-limiting in immunocompetent individuals, but decision to treat may be based on risk of inoculation (to self or others via open lesion or sexual transmission in the case of genital lesions). If one chooses to treat molluscum contagiosum, management options include cryotherapy, curettage, Ycanth (cantharidin) topical solution, podophyllotoxin, or Zelsuvmi (berdazimer sodium). Limited data is available for other therapies (e.g., imiquimod, potassium hydroxide, salicylic acid, and topical retinoids).

Ycanth (cantharidin 0.7% topical solution) is indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

- Ycanth (cantharidin) is administered only by health care providers who have received instruction and training prior to preparation and administration of Ycanth (cantharidin). Providers apply a single application of Ycanth (cantharidin) to each lesion every 3 weeks as needed. The topical solution can be removed with soap and water 24 hours after treatment.
- Ycanth (cantharidin) is for topical use only. Ycanth (cantharidin) is not for oral, mucosal, or ophthalmic use.
- The safety and efficacy in pediatric individuals below the age of 2 years have not been established.
- The safety and efficacy of drug use for longer than 12 weeks has not been established.
- The maximum number of applications of Ycanth (cantharidin) studied was 4 (on days 1, 21, 42 and 63).

Definitions

"Immunocompetent" means having a functional immune system, not weakened by disease or medication.

"Immunosuppression" refers to a state where the immune system is suppressed, either by specific conditions like HIV, medications, or malignancies.

"Molluscum Contagiosum" is a viral skin infection caused by the molluscipox virus resulting in small, raised, typically painless bumps on the skin.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Molluscum contagiosum

The Plan considers Ycanth (cantharidin) medically necessary when ALL of the following criteria are met:

1. The member is 2 years of age or older; *AND*
2. The member has a diagnosis of molluscum contagiosum.

If the above prior authorization criteria are met, Ycanth (cantharidin) will be approved for up to 12-weeks, up to 4 applications, with repeat applications no more frequently than every 3 weeks.^[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Molluscum Contagiosum

The Plan considers Ycanth (cantharidin) medically necessary when ALL of the following criteria are met:

1. Partial response evidenced by reduction in number or size of lesions but with some remaining; *AND*
2. At least 3 weeks have passed since the last application; *AND*
3. Total duration of therapy has not exceeded 4 applications.

NOTE: In clinical trials, patients received up to 4 applications of Ycanth (cantharidin) at intervals of approximately 21 days. Reauthorization requires evidence of continued benefit and allows retreatment within studied limits.

If the above reauthorization criteria are met, the requested product will be authorized for up to a maximum of 4 total applications.^[§]

Experimental or Investigational / Not Medically Necessary^[§]

Ycanth (cantharidin) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Condylomata Acuminata, another term for genital warts, referring specifically to the raised, cauliflower-like appearance that these warts can have. They are caused by HPV and are not the same as molluscum contagiosum.
- Genital Warts, warts that appear on the genitalia and are caused by certain strains of HPV. They are not the same as molluscum contagiosum.
- Papilloma Viral Infection, benign tumors that arise from epithelial tissues and are caused by various types of the human papillomavirus (HPV).
- Sexually Transmitted Disease (STD), a broad category of diseases that are primarily transmitted through sexual contact. Both molluscum contagiosum and genital warts (caused by HPV) can be considered STDs, but the term STD includes many other diseases as well, such as chlamydia, gonorrhea, and HIV, to name a few. This does not apply to cases of molloscum contagiosum that are sexually transmitted.
- Verruca (Warts), another term for warts. These are caused by HPV and are distinct from molluscum contagiosum.
- Verruca Vulgaris, i.e., common warts, typically seen on the hands and fingers. They are caused by the human papillomavirus (HPV) and are not the same as molluscum contagiosum.

Applicable Billing Codes

Table 1

CPT/HCPCS codes for Molloscum Contagiosum considered medically necessary if criteria are met:

<i>Code</i>	<i>Description</i>
17110	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettetment), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
17111	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettetment), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; 15 or more lesions
46900	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; chemical

46924	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), extensive (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery)
54050	Destruction of lesion(s), penis (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; chemical
54065	Destruction of lesion(s), penis (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), extensive (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery)
56501	Destruction of lesion(s), vulva; simple (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery)
56515	Destruction of lesion(s), vulva; extensive (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery)
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)

Table 2	
ICD-10 diagnosis codes considered medically necessary for Molluscum Contagiosum with Table 1 (CPT/HCPCS) codes if criteria are met:	
<i>Code</i>	<i>Description</i>
B08.1	Molluscum contagiosum

Table 3	
ICD-10 diagnosis codes for Molluscum Contagiosum considered NOT medically necessary with Table 1 (CPT/HCPCS) codes:	
A51	Early syphilis
A51.3	Secondary syphilis of skin and mucous membranes
A54	Gonococcal infection
A54.0	Gonococcal infection of lower genitourinary tract without periurethral or accessory gland abscess
A54.6	Gonococcal infection of anus and rectum
A56	Other sexually transmitted chlamydial diseases

A56.3	Chlamydial infection of anus and rectum
A60	Anogenital herpesviral [herpes simplex] infections
A60.0	Herpesviral infection of genitalia and urogenital tract
A60.1	Herpesviral infection of perianal skin and rectum
A60.9	Anogenital herpesviral infection, unspecified
A63	Other predominantly sexually transmitted diseases, not elsewhere classified
A63.0	Anogenital (venereal) warts
A63.8	Other specified predominantly sexually transmitted diseases
A64	Unspecified sexually transmitted disease
A66	Yaws
A66.1	Multiple papillomata and wet crab yaws
B00	Herpesviral [herpes simplex] infections
B00.8	Other forms of herpesviral infections
B00.9	Herpesviral infection, unspecified
B07	Viral warts
B07.0	Plantar wart
B07.8	Other viral warts
B07.9	Viral wart, unspecified
C51	Malignant neoplasm of vulva
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.8	Malignant neoplasm of overlapping sites of vulva
C51.9	Malignant neoplasm of vulva, unspecified
C60	Malignant neoplasm of penis
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis

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Clinical Guideline Revision / History Information

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