Abbreviated Drug Review

Ycanth™ (cantharidin)

Indications

- Topical treatment of molluscum contagiosum (MC) in adult and pediatric patients 2 years of age and older.

Dosage

- Apply contents of a single-use ampule (approximately 0.45 ml of a 0.7% cantharidin solution) directly to each lesion every 3 weeks as needed.
- Do not use more than two applicators during a single treatment session.
- Remove with soap and water 24 hours after treatment.

Special Instructions:

- For topical use only. Not for oral, mucosal, or ophthalmic use.
- All healthcare professionals should receive instruction and training prior to preparation and administration.

Background

- A naturally occurring terpenoid compound extracted from blister beetle used medicinally to treat MC for over 70 years but never formally approved by FDA
- Molluscum contagiosum is a viral skin lesion that presents as a painless, flesh-colored 3-5 mm diameter papule that typically resolves in a few months without treatment
- Pharmacologic treatments for molluscum contagiosum are not funded for adults or children (Oregon Prioritized List Line 613)

Efficacy

Approval by the FDA was obtained with data from two identical, phase 3, randomized, double blind, placebo vehicle-controlled, multicenter trials conducted over 12 weeks. The trials included 528 patients at least 2 years of age diagnosed with molluscum contagiosum by physical exam by investigators with appropriate clinical expertise. Those with immunosuppressive conditions (e.g., human immunodeficiency virus) or on systemic immunosuppressive therapy within prior 14 days or had lesions within 10 mm of a mucosal area at baseline were excluded. Patients were to receive a single 24-hour administration of YCANTH or matching placebo vehicle every 3 weeks until complete clearance achieved or for a maximum of 4 treatments. Patients (or caregivers) were to remove study drug with soap and water 24 hours after treatment or if treatment-emergent adverse events (TEAEs) occurred such as significant pain or blistering. The primary efficacy endpoint was the proportion of cantharidin-treated participants achieving complete clearance of all treatable baseline and new molluscum lesions at the end of the study. The secondary endpoint was the proportion of cantharidin-treated participants achieving complete clearance of all treatable baseline and new molluscum lesions at each visit. Patients with missing clearance data at the end of study period (day 84) were considered as not achieving clearance. Baseline characteristics were similar between groups in both trials and both males and females were equally represented. Most participants were aged 2 to 11 (89%), White (91%), had history of atopic dermatitis (AD) (16%) or active AD as determined by concomitant medication (8%), with a mean lesion count of roughly 21.

Table 1. Percentage of Subjects Exhibiting Complete Clearance of Treatable Molluscum Contagiosum Lesions

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

Key: CI=confidence Interval; NS = non-significant

Safety

Common adverse reactions: vesicles* (96%), pain** (63%), pruritis** (56%), scab** (48%), erythema** (46%), discoloration* (33%), dryness* (21%), edema* (10%), erosion* (7%), contact dermatitis (1%).
Contraindications: none
Warnings and precautions: Avoid application near eyes, mucosal tissue, or healthy skin. Possibilities of life threatening or fatal toxicities with oral use, ocular toxicity with eye contact, and local skin reactions possible with inappropriate administration. Cantharidin is a flammable liquid, even after drying. Avoid fire, flame or smoking near lesion(s) during treatment and after application until removed.
Special Populations: Has not been studied in children <2 years of age, in pregnant women, or in geriatric patients.
Key: *= at application site only; **= generalized and/or at application site

Evidence Gaps/Limitations

- No studies found to support evidence for use in the treatment of Oregon Health Plan (OHP) funded conditions.

Recommendation

- Apply Drugs for Non-funded Conditions prior authorization criteria to limit use to funded indications.

References

1. Ycanth (cantharidin) Prescribing Information. Verrica Pharmaceuticals, Inc. West Chester, PA. July 2023.
2. Eichenfield LF, McFalda W, Brabec B, et al. Safety and Efficacy of VP-102, a Proprietary, Drug-Device Combination Product Containing Cantharidin, 0.7% (w/v), in Children and Adults with Molluscum Contagiosum: Two Phase 3 Randomized Clinical Trials. JAMA Dermatol. 2020;156(12):1315–1323.

Drugs for Non-funded Conditions

Goal:

- Restrict use of drugs reviewed by the Oregon Pharmacy & Therapeutics (P&T) Committee without evidence for use in Oregon Health Plan (OHP)-funded conditions. Allow case-by-case review for members covered under the EPSDT program.

Length of Authorization:

- Up to 6 months.

Requires PA:

- A drug restricted by the P&T Committee due to lack of evidence for conditions funded by the OHP.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is the drug being used to treat an OHP-funded condition?	**Yes:** Go to #4	**No:** For current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP. For current age < 21 years: Go to #3
3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	**Yes:** Approve for 6 months, or for length of the prescription, whichever is less	**No:** Pass to RPh; Deny; medical necessity.
4. Pass to RPh. The prescriber must provide documentation of therapeutic failure, adverse event, or contraindication alternative drugs approved by FDA for the funded condition. Otherwise, the prescriber must provide medical literature supporting use for the funded condition. RPh may use clinical judgement to approve drug for up to 6 months or deny request based on documentation provided by prescriber.		

P&T / DUR Review: *12/22; 4/22 (SS); 11/15*
Implementation *1/1/23; 1/1/16*