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Drug Class Review: Topicals for Molluscum Contagiosum

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End Date of Literature Search: 01/06/2025

Purpose for Class Review:

To evaluate evidence for treatment of molluscum contagiosum, which is not currently funded on the 2025 Health Evidence Review Commission (HERC) List of Prioritized Health Services, and to develop specific prior authorization (PA) criteria for medical necessity and appropriateness of drugs that are Food and Drug Administration (FDA)-approved to treat molluscum contagiosum.

Plain Language Summary:

- The molluscum contagiosum virus generally causes a mild skin infection in children and adults. The virus can spread by skin-to-skin contact or by contact with an object that has the virus on it, such as a used towel, washcloth, or shared clothing. MC appears as small, skin-colored bumps on the skin that will usually heal on their own after a few months.
- Most providers wait to see if molluscum contagiosum treatment will heal on its own because many of the treatments may cause pain or skin discoloration. Sometimes patients with molluscum contagiosum are treated to stop the spread of infection to other body areas or to other people. Patients with weak immune systems may need treatment to prevent infections that could worsen their health.
- Effective treatment for molluscum contagiosum may include cutting away the skin infection or use of topical medicines applied to the affected area of the skin. However, these procedures do not cure molluscum contagiosum and there are no current care guidelines for providers to follow.
- Cantharidin and berdazimer, are 2 topical medicines approved by the Food and Drug Administration to treat molluscum contagiosum.
- Two studies with cantharidin showed that when about 3 people were treated with cantharidin for 12 weeks, one person would have complete clearance of molluscum contagiosum skin infection.
- In 3 studies with berdazimer, results were mixed. One study showed that when about 8 people were treated with berdazimer for 12 weeks, one person had complete clearance of molluscum contagiosum skin infection. Two studies did not show a clear benefit with use of berdazimer compared to no medicine.
- Providers must explain to the Oregon Health Authority why their patient needs a medicine to treat molluscum contagiosum before Oregon Health Plan will pay for it. This process is called prior authorization.

Research Questions:

1. What is the comparative efficacy and effectiveness of FDA-approved treatments (cantharidin topical solution 0.7%; berdazimer gel 10.3%) for severe infections caused by the molluscum contagiosum (MC) virus?
2. What is the evidence for harms of agents used to treat MC?
3. Is there comparative evidence to demonstrate meaningful differences in effectiveness or harms in certain subpopulations based on patient or disease characteristics (e.g., age, diagnoses, symptom severity)?

Conclusions:

- There was one systematic review that evaluated comparative efficacy and safety of select treatments for MC.¹ There was moderate-quality evidence that imiquimod 5% topical cream was no more effective than its vehicle in clinical cure or short-term improvements, however, imiquimod 5% topical cream may result in more harms such as application site reactions.¹ There was insufficient evidence to assess differences between treatments or for other drugs used off-label to treat MC lesions.¹
- The FDA recently approved two new agents for the treatment of MC: cantharidin topical solution 0.7% (YCANTH) and berdazimer gel 10.3% (ZELSUVMI).²⁻⁵
- Data from 2 identical, phase 3, randomized, double blind, placebo-controlled, multicenter trials conducted over 12 weeks demonstrated that in patients treated with cantharidin 0.7% topical solution there was a 30-40% difference in the proportion of patients who achieved complete clearance of MC lesions compared to patients treated with placebo vehicle (CAMP-1: 46.3% vs. 17.9%, respectively; CAMP-2: 54.0% vs. 13.4%, respectively; P < .001 for both trials; low-quality evidence).^{2,3,6} Refer to **Table 3** for specific results.
- Berdazimer was evaluated in three phase 3, 12-week, randomized, double-blind, placebo-controlled trials in patients with MC. In the B-SIMPLE4 trial, complete clearance of all MC lesions at 12 weeks was observed in a greater proportion of patients treated with berdazimer 10.3% topical gel compared to people treated with placebo (32.4% vs. 19.7%, respectively; treatment difference 12.7%; p < 0.001; low-quality evidence).^{4,5,7} In 2 other trials, berdazimer failed to reach statistical significance in the primary outcome measure of MC lesion clearance compared to placebo.^{5,7}
- Adverse reactions that were reported in clinical trials (≥1%) for both cantharidin and berdazimer included, but were not limited to, pain, vesicle formation, pruritus, erythema, and skin discoloration (**Table 8** summarizes specific adverse events).²⁻⁷

Recommendations:

- Create a new Preferred Drug List (PDL) class for agents to treat molluscum contagiosum.
- Add cantharidin topical solution 0.7% (YCANTH) and berdazimer gel 10.3% (ZELSUVMI) to the Molluscum Contagiosum Drugs PDL class.
- Implement PA criteria for cantharidin and berdazimer to establish specific medical necessity and appropriateness criteria for members with the Early Periodic Screening Diagnostic and Treatment (EPSDT) Benefit.

Background:

Molluscum contagiosum is a common, highly contagious, benign skin infection caused by a DNA poxvirus.^{8,9} MC is commonly observed in younger children but may also occur in older children and adults.^{8,9} Prevalence of MC for children in the United States is estimated to be less than 5% (roughly 8% worldwide) with the largest incidence in children aged 0 to 14 years.^{8,9} There do not appear to be gender differences in the frequency of MC infection.⁹ Transmission of the virus can occur via autoinoculation, through close physical contact with an infected individual, or by passive vector.¹⁰ The risk for MC infection may be higher in immunocompromised patients or in warm, moist areas where the virus tends to thrive such as community swimming pools or day care centers, and during close physical contact.^{8,11} Some research has identified that atopic dermatitis may be a risk factor for MC, but the relationship is uncertain.¹² Once infected, the incubation period ranges from 2 to 6 weeks.¹¹ Most cases of MC are self-limiting and will resolve without treatment in 6 to 18 months but some cases may persist for years.^{8,9,11}

Molluscum contagiosum is characterized by individual or multiple small flesh-colored raised papules with central umbilication or dimpled center.^{8,11} The papules typically present on the trunk, axillae, and extremities except for the soles of the feet and palms of hands.^{8,11} The virus may appear as a single lesion or up to 30 lesions that can range from 1 millimeter up to 1 centimeter in size.^{8,11} In children, MC is more commonly found on the trunk and limbs.⁸ In adults, MC may arise in the genital area and be transmitted by sexual contact.¹¹ Although mostly asymptomatic, patients may experience pruritus or tenderness in the affected

area(s).^{8,11} Immunocompromised patients may experience more widespread, larger (≥ 15 mm diameter) MC lesions that extend to atypical regions such as the neck, face, and eyelids.^{8,11}

MC virus (MCV) replication takes place in the cytoplasm of infected epidermal cells.^{10,11,13} There are 4 different known genotypes: MCV-1, MCV-2, MCV-3, and MCV-4.^{10,13} The most common genotype is MCV-1 which occurs in 76% to 97% of diagnosed individuals.¹³ As infected cells mature, they increase in size and migrate to the surface.^{10,11,13} Cells eventually become overrun by the virus and develop the characteristic molluscum bodies that exist in 3 or 4 layers above the basal cells themselves.¹¹ Molluscum contagiosum virus maturation takes place in about 5 days.¹¹ There is typically little to no inflammation present in undisturbed lesions which indicates that, in immunocompetent hosts, the virus is undetectable for most of the infection period.¹¹ However, once detected MCV elicits a powerful immune response by the host.^{11,13} The presence of severe, persistent MC lesions may be indicative of advanced disease in HIV positive patients due to the depletion of CD-4 T-helper lymphocytes.^{11,13}

There is no known cure for MC and there are no established care guidelines for the management of molluscum contagiosum. For non-mucosal and non-genital MC, medical procedures and pharmaceutical options are limited and have demonstrated varied levels of success.^{8,11} Although evidence to support symptomatic treatment is limited, patients may seek treatment for cosmetic concerns, to reduce discomfort, lessen chance of autoinoculation, avoid viral transmission to family and friends, or to prevent secondary infections.¹⁴ Common treatment options may include topical agents (see **Table 1**), cryotherapy, or surgical mechanical procedures to eradicate MC lesions.^{8,11} Cryotherapy is liquid nitrogen applied directly to the lesion to freeze the virus.^{8,11,15} Treatment via cryotherapy may require multiple applications every 2 to 3 weeks until complete resolution is attained.^{8,11,15} Curettage employs the use of a small device to cut away and remove MC lesions.^{8,11,15} This method may be a reasonable option in older children and adult populations in non-sensitive areas where the lesion count is minimal.^{8,11,15} There is a potential for pain, bleeding, blistering, scarring and/or and dyspigmentation associated with cryotherapy and curettage.^{8,11,15} Another mechanical method known as pulsed dye laser therapy may be used as a second-line option for difficult-to-treat MC, but the potential for skin discoloration and relatively high cost greatly limits its widespread use.^{11,15} There have been few randomized controlled trials (RCTs) of topical agents to treat MC lesions. Imiquimod 5% cream has been studied for off-label treatment of MC lesions in adult patients who were refractory to previous therapy, but the data to support efficacy were mixed and inconclusive.^{1,16} Selected off-label drug therapies and non-pharmacologic treatments are summarized in **Table 1**.^{1,8,11}

Table 1. Non-pharmacologic and Off-Label Drug Interventions for Molluscum Contagiosum^{1,8,11}

Intervention	Protocol	Common Adverse Effects
Cryotherapy	Liquid nitrogen applied to each lesion for 10-20 seconds for 1 or 2 cycles; may repeat after 1 week	Pain, burning, dyspigmentation, erythema, vesicles/bullae, scarring
Curettage	Scraping away of lesions via curette	Pain, anxiety, bleeding, scarring
Pulsed dye laser	Each lesion receives single pulse; may repeat after 2-3 weeks	Pain, pruritus, dyspigmentation
Benzoyl peroxide 10% cream	Applied to each lesion twice daily for 4 weeks	Mild dermatitis
Cimetidine	Oral dose 40 mg/kg daily in 2 or 3 divided doses for 2 months	Drug interaction potential
Imiquimod 5% cream	Applied to skin for 8 hours duration then washed off; repeat 3 to 5 times weekly until resolution for up to 16 weeks	Pain, burning, erythema, pruritus, ulceration, dyspigmentation
Phenol 10%	Lesions pierced with sharp instrument laced with phenol	Scarring
Podophyllotoxin 0.3-0.5% cream	Applied twice daily for 3 days, wait 4 days, then repeat. Continue for up to 4 weeks.	Erythema, pruritus

Potassium hydroxide aqueous solution 5-10%	Apply to lesions with cotton swab twice daily until superficial ulceration/inflammation	Dyspigmentation, mild stinging
Retinoic acid 0.5% cream	Applied to each lesion twice daily for 4 weeks	Mild dermatitis
Salicylic acid gel 12%	Applied to each lesion once or twice weekly for 4 weeks	Mild pain, stinging

There are 2 FDA-approved topical medications that can be used to treat MC lesions: cantharidin solution and berdazimer gel.^{2,4} **Table 2** is a summary of the FDA-approved indications and dosing for berdazimer gel and cantharidin topical solution.^{2,4}

Table 2. Indications and Dosing of Cantharidin and Berdazimer.^{2,4}

Drug Name (Trade name)/ Manufacturer	Indication(s)	Strength/Route	Dose and Frequency
Cantharidin (YCANTH)/ Verrica Pharmaceuticals	Topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.	0.7% Topical solution	Apply a single application 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.
Berdazimer (ZELSUVMI) EPIH SPV	Topical treatment of molluscum contagiosum in adults and pediatric patients 1 year of age and older	10.3% Topical gel	Mix together per dosing guide and immediately apply a thin layer once daily to each molluscum contagiosum lesion for up to 12 weeks.

A summary of relevant drug information is available in **Appendix 1**, which includes pharmacology and pharmacokinetic characteristics of these drugs, contraindications, warnings, and precautions, including any Black Boxed Warnings and Risk Evaluation Mitigation Strategies.

Methods:

A Medline literature search for new systematic reviews and RCTs assessing clinically relevant outcomes to active controls, or placebo if needed, was conducted. The Medline search strategy used for this review is available in **Appendix 2**, which includes dates, search terms and limits used. The OHSU Drug Effectiveness Review Project, Agency for Healthcare Research and Quality (AHRQ), National Institute for Health and Clinical Excellence (NICE), Department of Veterans Affairs, Canada’s Drug Agency (CDA-AMA), Scottish Intercollegiate Guidelines Network (SIGN), and Oregon Mental Health Clinical Advisory Group (MHCAG) resources were manually searched for high quality and relevant systematic reviews. When necessary, systematic reviews are critically appraised for quality using the AMSTAR tool and clinical practice guidelines using the AGREE tool. The FDA website was searched for new drug approvals, indications, and safety alerts.

The primary focus of the evidence is on high quality systematic reviews and evidence-based guidelines. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources.

Systematic Reviews:

Cochrane - Interventions for Cutaneous Molluscum Contagiosum¹

The use of topical and systemic interventions used to treat molluscum contagiosum lesions in children and adults was evaluated in a 2017 Cochrane review.¹ There were 22 studies identified (N=1650) that compared interventions (topical, surgical, systemic, or combination treatments) versus placebo (or waiting for natural

resolution) in immunocompetent patients with cutaneous, non-genital molluscum contagiosum.¹ Cantharidin and berdazimer were not included in the review. The primary outcome was short-term clinical cure (defined as complete clearance) of MC lesions up to 3 months after start of treatment.¹ Medium and long-term clinical cure rates, recurrence, adverse effects, and disease-related quality of life were assessed as secondary outcomes.¹

Most studies had insufficient information to assess risk of bias and had unclear risk of bias related to allocation concealment and selective reporting.¹ Only 5 of the studies had low risk of bias, and the majority of included studies involved imiquimod 5% topical cream.¹ Imiquimod 5% topical cream was similar to placebo for the outcome of short-term clinical cure based on moderate quality evidence.¹ Low quality evidence demonstrated that 5% imiquimod was less effective than cryotherapy for short-term clinical cure.¹ Imiquimod 5% topical treatment had higher rates of application site reactions (e.g. pain, erythema, burning, etc.), but treatment did not lead to serious adverse effects (moderate-quality evidence).¹ There was insufficient evidence to assess differences between various treatments or for other drugs used off-label to treat MC lesions.¹

After review, 2 systematic reviews were excluded due to poor quality (e.g., network meta-analyses), wrong study design of included trials (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical).^{17,18}

Guidelines:

High Quality Guidelines:

None identified.

Randomized Controlled Trials:

A total of 63 citations were manually reviewed from the initial literature search. After further review, 61 citations were excluded because of wrong study design (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical). The remaining trials are summarized in **Table 2** and **Table 3**. Full abstracts are included in **Appendix 2**.

Cantharidin 0.7% solution (YCANTh™) for topical treatment is a drug-device combination product approved to treat MC in patients 2 years of age and older.² Cantharidin is a naturally occurring terpenoid compound extracted from the blister beetle which has been used medicinally to treat MC for over 70 years, but until recently was never formally approved by FDA for that indication.¹⁹ Cantharidin acts as a vesicant but its mechanism in the treatment of MC lesions is unknown.^{3,6} FDA approval was obtained with data from two identical, phase 3, randomized, double blind, placebo vehicle-controlled, multicenter trials conducted over 12 weeks (CAMP-1 and CAMP-2).^{2,3,6} Patients were treated once every 3 weeks until complete lesion clearance was achieved or a maximum of 4 applications was administered.^{3,6} The primary efficacy endpoint was the proportion of cantharidin-treated participants achieving complete clearance of all treatable baseline and new molluscum lesions after 12 weeks.^{3,6} Enrolled patients were mostly 11 years of age or younger (~90%) with a mean age of 7.5 years, White (~90%), and had a mean of 22 and 19 MC lesions at baseline for the two trials.^{3,6} There were equal proportions of male and female participants.^{3,6} About 16% of participants had a history of atopic dermatitis, and over 50% of the patients required at least 4 treatments.^{3,6} Over the 2 trials, cantharidin 0.7% topical solution demonstrated a 30-40% difference in the proportion of patients who achieved complete clearance of MC lesions compared to patients treated with placebo vehicle (low-quality evidence).^{2,3,6} Additional details regarding CAMP1 and CAMP-2 trials may be found in **Table 3** below.

Table 3. Cantharidin Clinical Trials Summary^{3,6}

Study	Comparison	Population	Primary Outcome	Results	Notes/Limitations
CAMP-1 (N=266)		Male and female patients at least	Difference in proportion of patients who achieved	Cantharidin: 46% Vehicle: 18%	Trials used total body lesion count, so the number of treatments needed

		2 years of age diagnosed with MC.	complete clearance of all treatable baseline and new molluscum lesions at week 12 (day 84).	MD: 29% (95% CI 19% to 38%); P<0.001	for clearance per lesion is unknown (individual molluscum lesions were not tracked). Long-term efficacy and safety of cantharidin use beyond 12 weeks in the treatment of MC is unknown.
CAMP-2 (N=262)	Cantharidin topical solution 0.7% vs. placebo vehicle			Cantharidin: 54% Vehicle: 13% MD: 40% (95% CI 30% to 51%); P<0.001	

Berdazimer 10.3% topical gel (ZELSUVMI) is approved for the treatment of MC in patients at least 1 year of age.⁴ Berdazimer sodium gel when mixed with a proton-donating hydrogel is a nitric oxide-releasing agent.^{4,5} The mechanism of action for berdazimer gel in the treatment of MC is unknown.^{4,5,7} FDA approval was obtained with data from three phase 3, randomized, double-blind, vehicle-controlled trials in patients with MC over 12 weeks (Trials B-SIMPLE1/B-SIMPLE2/B-SIMPLE4).^{5,7} The primary endpoint was the difference in the percentage of patients treated with berdazimer achieved complete clearance of all treatable MC lesions (lesion count = 0) at week 12 compared to placebo vehicle.^{4,5,7} The mean age of participants was 6.5 years, most were White (85.5%), with roughly equal representation of males and females.^{5,7} In B-SIMPLE4, the baseline MC lesion count was slightly higher in the berdazimer gel group compared to vehicle (23.1 and 20.5, respectively).^{5,7} In the B-SIMPLE4 trial, complete clearance of all MC lesions at 12 weeks was observed in a greater proportion of patients treated with berdazimer 10.3% topical gel than vehicle recipients (32.4% vs. 19.7%, respectively; treatment difference 12.7%; p < 0.001; low-quality evidence).^{4,5,7} Trials B-SIMPLE1 and B-SIMPLE2 failed to reach statistical significance in the primary outcome measure.^{5,7} Details regarding B-SIMPLE trials 1, 2, and 4 may be found in **Table 4**. Although the observed treatment effect in the B-SIMPLE1 and B-SIMPLE2 trial was smaller than in the B-SIMPLE4 trial, the FDA recommended approval based on results of a post-hoc sensitivity analysis and a treatment effect trending in favor of the berdazimer gel.⁵

Table 4. Berdazimer Clinical Trials Summary^{5,7}

Study	Comparison	Population	Primary Outcome	Results	Notes/Limitations
B-SIMPLE1 (N=352)	Berdazimer gel 10.3% vs. placebo vehicle	Male and female patients 6 months and older with 3 to 70 MC lesions	Difference in proportion of patients who achieved complete clearance of all treatable MC lesions (lesion count = 0) at week 12	Berdazimer: 25.8% Vehicle: 21.6% MD: 4.3% (95% CI -5% to 18.6%); P=0.3637 <i>Not Statistically Significant</i>	Two of the 3 trials did not demonstrate efficacy on the primary endpoint. Efficacy in patients with sexually transmitted MC is unknown. Concomitant use with other topical therapies for MC was not evaluated. Long-term efficacy and safety of berdazimer use beyond 12 weeks in the treatment of MC is unknown.
B-SIMPLE2 (N=355)				Berdazimer: 30% Vehicle: 20.3% MD: 9.2% (95% CI -0.04% to 18.4%); P=0.0510 <i>Not Statistically Significant</i>	
B-SIMPLE4 (N=891)				Berdazimer: 32.4% Vehicle: 19.7% MD: 12.7% (95% CI 7.1% to 18.6%); P<0.0001	

Abbreviations: MD = mean difference; MC = molluscum contagiosum

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Appendix 1: Specific Drug Information

Table 5. Clinical Pharmacology and Pharmacokinetics of Cantharidin and Berdazimer.²⁻⁵

Drug Name	Mechanism of Action	Absorption	Metabolism/Excretion	Pharmacokinetics
Cantharidin (YCANTH)	Cantharidin is a vesicant; the mechanism of action in the treatment of molluscum contagiosum is unknown.	Children 2 to 15 years of age: Systemic absorption negligible.	N/A	<ul style="list-style-type: none"> • Half-life: N/A • Cmax: N/A • AUC: N/A • Vd: N/A
Berdazimer (ZELSUVM1)	Berdazimer is a nitric oxide–releasing agent. The mechanism of action for the treatment of molluscum contagiosum is unknown.	Minimal to no systemic absorption.	N/A	<ul style="list-style-type: none"> • Half-life: N/A • Cmax: N/A • AUC: N/A • Vd: N/A

Table 6. Use in Specific Populations for Cantharidin and Berdazimer.^{2,4}

Drug Name	Pregnancy	Lactation	Pediatric Use	Geriatric Use
Cantharidin (YCANTH)	There are no available data to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. No animal reproduction studies were conducted. Systemic exposure to drug following topical administration was low; therefore, maternal use is not expected to result in fetal exposure to cantharidin.	Avoid application to areas with increased risk for potential ingestion by or ocular exposure to the breastfeeding child. There are no data on the presence of cantharidin in either human or animal milk, or the effects on the breastfed infant or on milk production. Breastfeeding not expected to result in exposure of the child to the drug due to the low systemic absorption.	For use in patients 2 years of age and older.	Drug has not been studied in geriatric patients.
Berdazimer (ZELSUVM1)	There are no available data on use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of berdazimer to pregnant rats and rabbits increased malformations in the presence of severe maternal toxicity.	There are no data on the presence of the drug or its metabolite in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for the drug and any potential adverse effects on the breastfed infant or from the underlying maternal condition.	For use in pediatric patients 1 year of age and older.	Clinical studies did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

Drug Safety:

Table 7. Warnings and Precautions for Cantharidin and Berdazimer.^{2,4}

Drug Name	Warning/Precaution
Cantharidin (YCANTH)	<p>-For topical use only. Not for oral, mucosal, or ophthalmic use. Life threatening or fatal toxicities can occur if administered orally.</p> <p>-Local skin reactions. Avoid application near the eyes and mucosal tissues, and to adjacent healthy skin. Avoid other topical products (e.g. creams, lotions, or sunscreen) on treated areas until 24 hours after treatment or until washing. If severe blistering, severe pain or other severe adverse reactions occur, remove prior to the recommended 24 hours after administration by washing with soap and water.</p> <p>-Flammable liquid (even after drying). Avoid fire, open flames, or smoking near lesion(s) during treatment and after application until removed.</p>
Berdazimer (ZELSUVM1)	<p>-Application Site Reactions. Application site reactions, including allergic contact dermatitis, have occurred in patients treated with this agent. Suspect allergic contact dermatitis in the event of pain, pruritus, swelling or erythema at the application site lasting longer than 24 hours. If allergic contact dermatitis occurs, discontinue drug and initiate appropriate therapy.</p>

Table 8. Adverse Reactions Reported in Clinical Trials (Incidence ≥1%) for Cantharidin and Berdazimer.^{2,4}

Description	Cantharidin	Berdazimer	
Occurred at Application Site	Pain	X	
	Vesicles	X	
	Pruritus	X	
	Scab	X	
	Erythema	X	
	Discoloration	X	
	Dryness	X	
	Edema/Swelling	X	
	Erosion	X	
	Exfoliation		X
	Dermatitis		X
	Irritation		X
	Infection		X
Pyrexia		X	
Contact dermatitis	X		
Vomiting		X	
Upper Respiratory Tract Infection		X	
Pain	X		
Pruritus	X		
Scab	X		
Erythema	X		

Appendix 2: Medline Search Strategy

Ovid MEDLINE(R) ALL 1946 to January 6, 2025

- 1) berdazimer.mp./24
- 2) exp Cantharidin/901
- 3) exp Molluscum Contagiosum/1564
- 4) 1 or 2/923
- 5) 4 and 5/62

Appendix 3: Key Inclusion Criteria

Population	Adults and children with molluscum contagiosum
Intervention	Topical therapies: Cantharidin, Berdazimer
Comparator	Placebo or active treatment
Outcomes	Molluscum lesion reduction, adverse reactions
Timing	Not applicable
Setting	Outpatient therapy

Appendix 4: Proposed Prior Authorization Criteria

Molluscum Contagiosum

Goal(s):

- Ensure that medications for molluscum contagiosum (MC) are used appropriately for OHP-funded conditions.
- Define medically appropriate and necessary therapy supported by the medical literature for members covered under the EPSDT program.

Length of Authorization:

- Up to 12 weeks

Requires PA:

- Cantharidin (pharmacy and provider administered claims) and berdazimer for pharmacy claims.

Table 1. FDA-Approved Dosing

Product Name (BRAND NAME)	Indication	Dosing and Duration	Maximum Duration
Cantharidin (YCANTH)	Topical treatment of molluscum contagiosum in adults and pediatric patients 2 years of age and older.	Apply a single application directly to each lesion every 3 weeks as needed; do not use more than 2 applicators during a single treatment session.	4 treatments
Berdazimer (ZELSUVMI)	Topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older.	Apply a thin even layer once daily to each lesion	12 weeks

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an FDA approved indication for the age and diagnosis submitted?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the diagnosis funded by OHP?	Yes: Go to #4	No: If not eligible for EPSDT review, Pass to RPh. Deny; not funded by the OHP. If eligible for EPSDT Review, Go to #4
4. Have the patient's lesions been present and unresolved for 6 months or longer?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness
5. Have the patient's lesions been previously treated with the requested agent?	Yes: Go to #6	No: Go to #7
6. Has the patient already received the maximum duration of therapy recommended in Table 1 ? <ul style="list-style-type: none"> • 4 or more treatment doses of cantharidin OR • 12 or more weeks of berdazimer 	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #7
7. Is the requested agent being prescribed by or in consultation with a dermatologist?	Yes: Go to #8	No: Pass to RPh. Deny; medical appropriateness
8. Has the provider performed an objective baseline assessment and determined one of the following: <ul style="list-style-type: none"> • The molluscum contagiosum lesions are extremely troublesome (e.g. pain, itching, etc.) OR • Patient is immunocompromised. 	Yes: Go to #9	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria		
9. Is the requested agent being used to treat lesions in or near the mouth, eyes, or mucosal tissues?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #10
10. Is the agent requested being used in combination with another treatment modality for MC (e.g. cryotherapy, curettage, or another agent listed in Table 1)?	Yes: Pass to RPh. Deny; medical appropriateness	No: Approve for up to 12 weeks Cumulative treatment not to exceed 12 weeks of therapy.

P&T/DUR Review: 6/25 (DE)
Implementation: 8/1/25