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Drug Class Review: Topical Moisturizers

Date of Review: December 2023 **End Date of Literature Search:** 10/04/2023

Plain Language Summary:

- People commonly apply skin moisturizers to prevent dry, scaly, itchy, or flaky skin. Dryness can cause the skin to break down which can lead to infections. Atopic dermatitis and ichthyosis are two types of skin disease that commonly have dry, scaly, itchy, or flaky skin.
- Evidence shows that moisturizers reduce disease severity in people with atopic dermatitis. The National Institute for Health and Care Excellence recommends emollients for children with atopic dermatitis.
- The National Institute for Health and Care Excellence also recommends topical products to prevent skin damage for people who have high risk for skin ulcers. Risk for skin damage is increased for people with swollen limbs, dry inflamed skin, who use of diapers, or who are unable to move. People at high risk for skin damage usually have more than one of these conditions.
- Evidence shows that moisturizers do not prevent development of atopic dermatitis in otherwise healthy infants unless there is a strong family history indicating increased risk for disease. Use of moisturizers in infants with healthy skin may increase risk for skin infections.
- There is no evidence that shows one moisturizer is better than another.
- The Oregon Health Authority (OHA) does not currently pay for moisturizers for people with Medicaid. We recommend that OHA begin to pay for moisturizers for people with severe skin disease. Before OHA will pay for a moisturizer, the provider should document disease severity.

Purpose for Class Review:
To evaluate whether skin emollients, protectants, or moisturizers should be added as covered medications to the fee-for service (FFS) benefit for funded conditions.

Research Questions:
1. What is the evidence for clinical efficacy for skin moisturizers, emollients, or protectants for treatment or prevention of skin conditions (e.g., dermatitis/eczema, ichthyosis)?
2. What is the evidence for harms of skin moisturizers, emollients or protectants in people with skin conditions?
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:
- Six systematic reviews evaluated efficacy of emollients for primary prevention of skin conditions and associated complications.
    - There was moderate quality evidence that skin care interventions in infants did not prevent development of eczema or atopic dermatitis compared to usual care at 1 to 3 years of age.[1-3] In studies of infants at high risk for development of AD based on family history, use of emollients decreased

risk compared to usual care (relative risk [RR] 0.75, 95% confidence interval [CI] 0.62 to 0.91, moderate-quality evidence) at 6 to 24 months, but use of emollients was also associated with increased risk of infection (67 vs. 50 per 1000; RR 1.33, 95% CI 1.01 to 1.75; moderate-quality evidence).[1,3]
    - Use of topical emollients or moisturizers in preterm infants may increase risk of infection (insufficient evidence), but likely has no impact on short-term mortality (over 2-4 weeks).[4]
    - There is insufficient evidence to assess whether moisturizers can help prevent occupational dermatitis of the hands.[5]
    - There is insufficient evidence to assess whether moisturizers can help maintain skin integrity and prevent skin damage in older people.[6]
- Compared to placebo or no treatment, moisturizers improved the following outcomes in people with atopic dermatitis or eczema:[7]
    - patient reported eczema severity (78% vs. 37%; RR 2.46, 95% CI 1.16 to 5.23; low-quality evidence),
    - provider reported disease severity (standardized mean difference [SMD] -0.65; 95% CI -0.89 to -0.41; high-quality evidence); and
    - people who experienced a flare (13% vs. 48%; RR 0.33, 95% CI 0.17 to 0.62; moderate-quality evidence).
- When moisturizers were added to active topical therapy, there were small improvements in provider reported disease severity that did not meet thresholds for clinically important differences (SMD -0.87, 95% CI -1.17 to -0.57; moderate-quality evidence).[7] There was low-quality evidence that combination use of moisturizer and active treatment reduced flares compared to just active treatment alone (31% vs. 13%; RR 0.43, 95% CI 0.20 to 0.93).[7] Guidance from the National Institute for Health and Care Excellence (NICE) recommends emollients for children with eczema or atopic dermatitis even when symptoms are controlled.[8]
- Guidance from NICE suggests use of a barrier preparation to prevent skin damage in adults at high risk of developing a moisture lesion or incontinence-associated dermatitis and infants or children who are incontinent. People at high risk for lesions usually have multiple risk factors (such as those with incontinence, limited mobility, nutritional deficiency, edema, dry or inflamed skin).[9] There was insufficient evidence to support one product or type of moisturizer over another for atopic dermatitis or dermatitis associated with incontinence.[7,10]
- There was insufficient evidence to evaluate efficacy or safety of moisturizers for chronic pruritus of unknown origin or infantile seborrheic dermatitis.[11,12]
- No high quality systematic reviews were identified that evaluated emollients for ichthyosis. European guidelines from 2019 recommend emollients for all forms of congenital ichthyosis based on low-quality evidence.[13]

Recommendation:

- Add coverage for select topical moisturizers with prior authorization (PA) for non-preferred products to limit coverage to funded conditions.
- Update benefit plan exclusion criteria to reflect coverage for moisturizers and review process for exceptions.
- There are no PDL recommendations for specific products based on the clinical evidence. After evaluation of costs in executive session, recommend coverage of creams, lotions and ointments. Make moisturizers preferred if they cost less than $0.05 per gram or milliliter. Make all other moisturizers non-preferred.

Background:

A variety of conditions cause dry, scaly, itchy or flaky skin. Common conditions include atopic dermatitis or eczema, psoriasis, xerosis, and contact dermatitis. The Health Evidence Review Commission (HERC) has recommended funding for only severe inflammatory skin conditions on the prioritized list of health services. Severe disease is defined based on functional impairment and involvement of hands, feet, face, mucus membranes, or at least 10% of the body surface area.[14]

Treatments for skin disease vary based on condition, but typically include a variety of topical options such as corticosteroids, calcineurin inhibitors, and retinoids. Systemic therapy may be recommended for severe symptoms and may include retinoids, immunosuppressants, or targeted immune modulators. These prescription medications are covered by fee-for-service (FFS). In some cases, PA criteria limits use to funded conditions based on disease severity.

Skin moisturizers are also commonly recommended to treat symptoms of dry, itchy, or flaky skin. Moisturizers can contain hydrophilic components, to help skin hydration, or lipophilic components, to prevent evaporation of water from the skin and assist skin barrier recovery.[7] Examples of common components include humectants to retain water (e.g., urea, glycerol, lactic acid), occlusives which form a layer on the skin and prevent water loss (e.g., petrolatum, dimethicone, and mineral oil), and emollients to soften the skin (e.g., lanolin, glycerol or glyceryl stearate, soy sterols).[7] While there are some prescription emollients available, the vast majority of products are available as only over-the-counter formulations. State Medicaid programs have more flexibility for coverage of over-the-counter medicines, and can elect to cover or exclude these drugs from their Medicaid drug program. Because mild and moderate skin disease are unfunded, skin moisturizers, with the exception of zinc oxide, have historically not been covered in FFS Medicaid. Beginning in January 2024, the Health Evidence Review Commission has modified the prioritized list to add congenital (or inherited) ichthyosis associated with severe symptoms to a funded line. This prompted re-evaluation of coverage for topical moisturizers.

Ichthyosis is characterized by hyperkeratoic, scaling skin.[15] It can be inherited or acquired. Acquired ichthyosis is more likely to present in adults. It can arise from a variety of circumstances including drugs, autoimmune or inflammatory conditions, infections, or endocrine and metabolic diseases. Acquired ichthyosis typically improves once the triggering conditions are resolved. Management of acquired ichthyosis is focused on treating the underlying cause.[15]

Inherited ichthyosis is caused by genetic mutations in proteins and lipids that maintain skin integrity.[15] It typically presents in infancy or early childhood. The most common type of inherited ichthyosis, ichthyosis vulgaris, is typically associated with light scaling and thickening of the skin on the palms and soles of the feet (called hyperlinear palmoplantar markings).[15] Other less common genetic defects can be associated with blistering, skin erosion, other organ involvement, or delayed development. Rare forms of ichthyosis, such as harlequin ichthyosis, are associated with restrictive, adherent scaling that limits mobility. Diagnosis is typically based on clinical presentation, family history, and/or skin biopsy.[15] Genetic testing may help confirm some of the more severe forms of the disease. Prognosis varies depending on severity of symptoms and type of ichthyosis. Common complications of the disease include heat intolerance from inability to sweat and complications of the ears and eyes.[15] Desquamated skin in the outer ear canal can lead to pain and impaired hearing, and ectropion, a condition where the lower eyelid turns outward, is common in people with ichthyosis.[15] Skin infections, growth delay, nutritional deficiency, decreased range of motion, and psychological symptoms are associated with more severe disease.[15]

The goal of treatment for inherited ichthyosis is symptom management to reduce complications of the disease. There is limited evidence for most treatments and many recommendations are based on expert opinion.[13] Non-pharmacologic treatment recommendations include regular bathing to soak the skin, mechanical desquamation of scales with a cloth or sponge, and multidisciplinary support from psychologists, dermatologists, otolaryngologists, and ophthalmologists.[13,15] Pharmacologic treatments include use of topical emollients and keratolytics, topical retinoids, or systemic retinoids for more severe symptoms that are unresponsive to topical therapy.[15] European guidelines from 2019 for the management of congenital ichthyosis recommend topical moisturizers for all ichthyoses.[13] Common options include petrolatum or petroleum jelly, urea, propylene glycol, lactic acid, and salicylic acid. There is insufficient information to support use of any specific product over another.[13,15,16] Moisturizers are applied *at least* twice daily after bathing, and therefore, patient preferences and tolerability can be a major factor contributing to therapy compliance.[13] There is mixed evidence for use of immunosuppressants for symptom improvement in patients with inherited ichthyosis. Topical steroids and topical calcineurin inhibitors may be considered for short-term flares, but caution is recommended with long-term use due to risks of systemic absorption and skin atrophy.[15] Systemic interleukin inhibitors have been studied for inherited ichthyosis, with limited results. A small randomized controlled trial (RCT) of secukinumab in adults with inherited ichthyosis demonstrated no improvement in symptoms or disease severity.[17]

There are over 150 unique types and combinations of topical moisturizers currently reported by First Databank, the company that Oregon Medicaid uses to supply drug information. In FFS, analysis of denied claims indicates that the most commonly prescribed moisturizers include zinc oxide, lanolin

alcohol/mo/w.pet/ceres (MINERIN), ammonium lactate, mixed zinc oxide formulations (zinc oxide/menthol, zinc oxide/cod liver oil), dimethicone, and mineral oil/petrolatum.

Methods:
A Medline literature search for new systematic reviews 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, and the Canadian Agency for Drugs and Technologies in Health (CADTH) 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 primary focus of the evidence is on high quality systematic reviews and evidence-based guidelines.

Systematic Reviews:
Emollients for Primary Prevention
Three high-quality systematic reviews evaluated emollients for prevention of atopic dermatitis (AD) in infants.[1-3] One of these reviews, a 2022 Cochrane systematic review, identified 33 studies (n=25,827) evaluating skin interventions in infants of which 11 evaluated outcomes of interest for eczema, food allergy and adverse events.[1] Included studies were primarily conducted in infants who were classified as having high risk for atopic dermatitis based on family history.[1] The primary comparison for most studies was skin care interventions (including use of emollients) compared to standard infant skin care (such as bathing without a specific intervention).[1] The specific emollient used varied between studies, and follow-up for studies ranged from 24 hours to 3 years.[1] There was moderate-quality evidence from 7 RCTs that skin care interventions (including use of emollients) did not prevent development of eczema compared to usual care at 1 to 3 years of age.[1] Use of skin care interventions also had no impact on time to onset of eczema compared to usual care based on moderate-quality evidence from 9 RCTs.[1] There was moderate-quality evidence that use of a skin care regimen increased risk for skin infection compared to usual care (67 vs. 50 per 1000; RR 1.33, 95% CI 1.01 to 1.75; 6 RCTs; n=2728).[1] Evidence for allergy-related outcomes was mixed and graded as low quality indicating uncertainty in treatment effects.[1]

The second systematic review evaluated emollients specifically for prevention of atopic dermatitis in infants less than 6 weeks of age. This review included many of the same studies as the Cochrane review, and found no difference in risk of development of AD compared to usual care (RR 0.84; 95% CI 0.64 to 1.10; I^2=60%; 10 RCTs; low quality evidence).[3] However, authors noted subgroup differences based on baseline risk for development of AD. In studies of infants at high risk for development of AD based on family history, authors noted that use of emollients decreased risk compared to usual care (RR 0.75, 95% CI 0.62 to 0.91, n=1033; 8 RCTs; I^2 = 10%; moderate-quality evidence) at 6 to 24 months.[3] There was no difference in development of food sensitization or allergy with use of emollients compared to standard care (RR 0.85; 95% CI 0.65 to 1.11; 5 RCTs; n=1455; moderate-quality evidence). An increased risk of skin infection with use of emollients was noted when compared to usual care (RR 1.34, 95% CI 1.03 to 1.75, 3 RCTs; I^2 = 100%).[3]

The third systematic review evaluating emollients for prevention of AD in infants found similar results. The authors concluded that emollients may not prevent AD in healthy infants, but may decrease risk for those at increased risk of development for AD.[2] All 3 of these systematic reviews noted substantial heterogeneity among studies including definitions for infants at risk for AD, criteria and timing of AD diagnosis, type of intervention and emollient used.[1-3] Included studies also had notable limitations including variable adherence to treatment, risk for attrition, lack of blinding and risk of reporting bias which contributed to uncertainty in results.[1-3]

A 2016 Cochrane review evaluated whether use of topical emollients or moisturizers decreased risk of infection or mortality in preterm infants. Infection is a major cause of morbidity and mortality in preterm infants.[4] The review identified 18 RCTs (n=3089) which assessed topical ointments, creams, and oils. All trials had risk for performance and detection bias as they were unblinded. About half of trials had unclear risk for selection bias because of inadequate methodologic reporting. Trials were generally of short duration and outcomes were typically assessed upon discharge from the hospital. There was low-quality evidence from 8 RCTs (n=2086) that topical ointments or creams did not decrease risk for invasive infection (RR 1.13, 95% CI 0.97 to 1.31) or mortality (RR 0.87, 95% CI 0.75 to 1.03) in preterm infants compared to routine skin care.[4] In a subgroup analysis of studies to high-income countries, there was risk of infection with use of ointments or creams compared to usual care (RR 1.25, 95% CI 1.04 to 1.50; NNH 17, 95% CI 9 to 100; 2 trials, 1210 infants).[4] There was no difference in invasive infection (low-quality evidence) or mortality (moderate-quality evidence) with use of plant or vegetable oils compared to usual care.[4] Trials had significant heterogeneity that was not explained by subgroup analyses evaluating participants based on gestational age at birth or study location.[4]

A 2018 Cochrane review evaluated moisturizers and barrier creams for prevention of occupational dermatitis of the hands.[5] While emollients are commonly used to prevent and improve skin symptoms, authors found insufficient evidence to confidently assess effectiveness of moisturizers and barrier creams.[5] Nine RCTs (n=2888) were included in the review and the primary outcome was development of irritant hand dermatitis.[5] Evidence was significantly limited by unclear risk for selection performance and reporting bias in included studies.[5] There was high heterogeneity related to how dermatitis was assessed, products used, occupations for involved participants, and duration of treatment. Participants included metal workers exposed to cutting fluids, dye and print factory workers, cleaners and kitchen workers, healthcare workers, hairdressers, and gut cleaners in swine slaughterhouses.[5] Study durations ranged from one month to 3 years.[5] Differences between groups were small, often below what would be considered a clinically important difference, and results were imprecise for all outcomes.[5] All outcomes were graded as low or very low quality indicating substantial uncertainty in the true treatment effect.[5]

A 2020 Cochrane review evaluated emollients to help maintain skin integrity in older people who were living in residential care settings.[6] Six RCTs were included in the review and evaluated a range of interventions including use of moisturizing soap, soaking with water, oil or lotion and application of leave-on moisturizers.[6] In most studies, average age of included participants was over 80 years.[6] In 2 RCTs, participants had dry skin and other trials recruited people who had otherwise normal skin.[6] Duration of trials ranged from 5 days to 6 months. Studies were generally small and had high risk for attrition, performance, and detection bias.[6] The primary outcome was frequency of skin damage which was reported in only one trial.[6] Overall, authors concluded that evidence was insufficient to determine whether use of moisturizers or regular skin hygiene regimens prevents skin damage or improves symptoms of dryness in older adults.[6]

<u>Emollients for Treatment</u>

A 2017 Cochrane review included 77 RCTs (n=6603) evaluating efficacy of moisturizers for treatment of atopic dermatitis or eczema.[7] About half of the included studies were single center studies, and RCTs were generally small (most included between 20 and 60 participants).[7] Most included participants had mild to moderate disease and very few studies evaluated similar types of moisturizers. Compared to placebo, vehicle or no treatment, moisturizers improved the number of patients who reported improved eczema severity (78% vs.37%; RR 2.46, 95% CI 1.16 to 5.23; I^2= 95%; number needed to treat [NNT] = 2; low-quality evidence), provider reported disease severity (SMD of -0.65; 95% CI -0.89 to -0.41; P< 0.00001; I^2 = 75%; high-quality evidence); and people who experienced a flare (13% vs. 48%; RR 0.33, 95% CI 0.17 to 0.62; P = 0.0006; I^2 = 73%; NNT = 4, 95% CI 3 to 5; moderate-quality evidence).[7] There was no difference in health-related quality of life or adverse events with moisturizers compared to placebo, vehicle or no treatment (low-quality evidence).[7] Moisturizers were directly compared in 22 RCTs with no strong evidence that any type of product improved flares, disease severity or quality of life more than another.[7] Six RCTs (n=648) evaluated whether addition of a moisturizer to other topical treatment (e.g., steroids or calcineurin inhibitors) improved symptoms over 2 to 4 weeks.[7] Patient reported disease severity was not assessed. Changes in provider-reported disease severity were statistically improved with combination treatment compared to

topical steroids alone, but did not meet thresholds for minimum clinically important differences (SMD -0.87, 95% CI -1.17 to -0.57; moderate-quality evidence).[7] One study small evaluating flares, documented that combination use of moisturizer and active treatment reduced flares compared to just active treatment alone (31% vs 13%; RR 0.43, 95% CI 0.20 to 0.93; NNT = 6, 95% CI 3 to 57; low-quality evidence).[7]

A 2016 Cochrane review included 13 RCTs (n=1295) evaluating efficacy of topical treatments for prevention and treatment of dermatitis associated with urinary or fecal incontinence in adults.[10] All trials were conducted in nursing homes or hospitals and 9 RCTs were single center studies.[10] Most RCTs had high or unclear risk of selection bias, were unblinded, and more than half had high or unclear risk for attrition bias.[10] Average age for enrolled participants was between 59 and 89 years of age, and 6 RCTs evaluated prevention of dermatitis, enrolling participants who did not yet have any symptoms of redness or skin erosion.[10] Interventions were grouped into 2 categories: skin cleansers and products intended to be left on the skin such as moisturizers and protectants.[10] There were direct comparisons for various topical leave-on products compared in 8 RCTs. Products included various zinc oxide formulations, dimethicone, petrolatum, Desitin (combination zinc oxide/lanolin/petrolatum/cod liver oil), Calmoseptine (combination zinc oxide/menthol/chlorothymol/ glucerine/lanolin/sodium bicarbonate/phenol/thymol).[10] There was no difference in incidence of dermatitis when comparing various products. Evidence was limited to a single trial for each comparison. Incidence of bacterial or fungal infections were rarely reported (2.8% of participants in one RCT). There was evidence from 2 trials that soap and water may be less effective than a skin cleanser (RR 0.39, 95% CI 0.17 to 0.87; 1 RCT; n=65; low-quality evidence) or washcloth with cleansing, moisturizing and protecting properties (RR 0.31, 95% CI 0.12 to 0.79; 1 RCT; n=121 moderate-quality evidence) for prevention and treatment of dermatitis associated with incontinence.[10]

A 2020 Cochrane review did not identify any eligible RCTs that evaluated emollients or cooling lotions for treatment of chronic pruritus of unknown origin.[11] Notably, this review excluded studies in which pruritus was caused by a known dermatological or systemic condition.[11] A 2019 Cochrane review evaluating efficacy of interventions for infantile seborrheic dermatitis found insufficient information to evaluate efficacy of emollients or moisturizers based on results from 2 small RCTs.[12]

After review, 10 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).

Guidelines:

High Quality Guidelines:

Guidelines from NICE make the following recommendations for use of moisturizers and emollients for prevention and treatment of skin conditions:

- For adults who are at high risk of developing a moisture lesion or incontinence-associated dermatitis (such as those with incontinence, edema, dry or inflamed skin), consider using a barrier preparation to prevent skin damage.[9] Risk is evaluated based on predisposing risk factors and skin assessment. People at high risk for pressure ulcers will usually have multiple risk factors (such as limited mobility, history of pressure ulcers, nutritional deficiency, or cognitive impairment). Skin assessment evaluates pain or discomfort, skin integrity, discoloration, and variations in heat, firmness or moisture.[9]
- For neonates, infants, children and young people who are incontinent, use barrier preparations to help prevent skin damage and moisture lesions.[9]
- For children with eczema or atopic dermatitis, emollients are the basis of management and should always be used, even when atopic eczema is clear.[8] Management can then be stepped up or down, according to the severity of symptoms, with the addition of the other active treatments (e.g., topical steroids, calcineurin inhibitors, phototherapy, or systemic therapy).[8] For prevention of secondary bacterial infections caused by eczema, recommendations are made to manage underlying disease and flares with treatments such as emollients and topical corticosteroids, whether antibiotics are offered or not.[18]

European guidelines for congenital ichthyosis were published in 2019.[13,19] A systematic literature search was conducted to evaluate current literature. However, very few RCTs or controlled trials were identified. Most articles identified were case reports or small series. Recommendations were categorized according to the level of evidence outlined in **Table 1.** Because of limited evidence, many recommendations are based on expert opinion.

Table 1. Evidence grades for guideline recommendations

Grade of Recommendation	Correlating level of evidence
A	At least one high quality systematic review or RCT (level 1 evidence) with low risk of bias and directly applicable to the target population
B	High quality systematic reviews of case-control or cohort studies (level 2 evidence), directly applicable to the target population and demonstrating consistent results OR evidence extrapolated from low quality systematic review or RCTs (level 1 evidence)
C	Well conducted case-control or cohort studies (level 2 evidence) with low risk of bias, directly applicable to the target population and demonstrating consistent results
D	Non-analytical studies like case reports or case series (level 3 evidence) or expert opinion (level 4 evidence)

Recommendations for use of topical products are outlined below:[13]

- Emollients should be used in all types of ichthyosis (level 1 evidence; Grade B).
- Emollients should be applied several times a day and ideally after bathing (level 3 evidence; Grade D).
- Occlusive moisturizers are unsuitable for hot climates because of risk for overheating (level 4 evidence; Grade D).
- Emollients containing urea are unsuitable for inflamed or eroded skin or on flexural areas (such as armpits, knees, elbows, or groin) (level 3 evidence; Grade D).
- Topical agents (such as keratolytics or retinoids) are recommended for thickened/hyperkeratotic skin (level 1 evidence; Grade B).
- Keratolytics should be avoided in people with inflamed or eroded skin, on the flexures and face (level 1 evidence; Grade B). Caution is recommended for infants due to risk of systemic absorption (level 3 evidence; Grade D). Topical retinoids are contraindicated in pregnancy (level 1 evidence; Grade B).

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Appendix 2: Medline Search Strategy

Ovid MEDLINE(R) ALL 1946 to October 04, 2023

1	emollient.mp.	1098
2	exp Emollients/	5707
3	1 or 2	6304
4	limit 3 to "systematic review"	78

Appendix 3: Key Inclusion Criteria

Population	People with severe skin inflammatory skin disease or ichthyosis
Intervention	Emollients, protectants, or moisturizers
Comparator	Placebo
Outcomes	Symptoms, disease severity, function, quality of life, skin infection

Setting	Outpatient

Appendix 4: Proposed Prior Authorization Criteria

Moisturizers, topical

Goal(s):

- Limit use to funded conditions. Allow case-by-case review for members covered under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program.

Length of Authorization:

- 12 months

Requires PA:

- Non-preferred topical emollients, protectants, or moisturizers

Covered Alternatives:

- Covered products include: topical lotions, ointments, and creams
- Preferred alternatives listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD 10 code.	
2. Is the request for treatment of severe skin disease? Severe disease is defined by the prioritized list as: • Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following: 1. At least 10% body surface area involved OR 2. Hand, foot, face, or mucous membrane involvement	**Yes:** Go to #4	**No: For age ≥ 21 years:** Pass to RPh; deny, not funded by the OHP **For age < 21 years:** Go to #3

Approval Criteria		
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:** Go to #4	**No:** Pass to RPh. Deny; medical necessity
4. Is the request for a preferred product?	**Yes:** Approve for 12 months	**No:** Go to #5
5. Has the patient failed to have benefit with (or have contraindications to) at least 2 preferred products?	**Yes**: Approve for 12 months	**No**: Pass to RPh. Deny; medical appropriateness.

P&T/DUR Review: *12/23 (SS)*
Implementation: *1/1/24*

Exclusion List

- Deny payment for drugs that are only FDA-approved for indications that are not covered by the Oregon Health Plan (OHP).
- Allow case-by-case review for members covered under the EPSDT program.
- Other exclusionary criteria are in rules at: https://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx

A full list of exclusions and limitations is listed in OAR 410-121-0147 Exclusions and Limitations (DMAP Pharmaceutical Services Program): https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=87

Examples of drugs which are not covered include (but may not be limited to):

- Expired drug products;
- Drug products from non-rebatable manufacturers, with the exception of selected oral nutritionals, vitamins, and vaccines;
- Active Pharmaceutical Ingredients (APIs) and Excipients as described by Centers for Medicare and Medicaid (CMS);
- Drug products that are not assigned a National Drug Code (NDC) number;
- Drug products that are not approved by the Food and Drug Administration (FDA);
- Non-emergency drug products dispensed for Citizenship Waived Medical client benefit type;
- Drug Efficacy Study Implementation (DESI) drugs;
- Medicare Part D covered drugs or classes of drugs for fully dual eligible clients

NOTE: Returns as "70 – NDC NOT COVERED"

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. For what reason is it being rejected?		
3. “70” NDC Not Covered (Transaction line states “Bill Medicare”	**Yes:** Go to the Medicare B initiative in these criteria.	**No:** Go to #4
4. “70” NDC Not Covered (Transaction line states “Bill Medicare or Bill Medicare D”	**Yes:** Informational PA to bill specific agency	**No:** Go to #5
5. “70” NDC Not Covered (due to expired or invalid NDC number)	**Yes:** Informational PA with message “The drug requested does not have a valid National Drug Code number and is not covered by Medicaid. Please bill with correct NDC number.”	**No:** Go to #6
6. “70” NDC Not Covered (due to DME items, excluding diabetic supplies) (Error code M5 –requires manual claim)	**Yes:** Informational PA (Need to billed via DME billing rules) 1-800-336-6016	**No:** Go to #7
7. “70” NDC Not Covered (Transaction line states “DESI Drug”)	**Yes:** Pass to RPh. Deny (DESI Drug) with message, “The drug requested is listed as a “Less-Than-Effective Drug” by the FDA and not covered by Medicaid.”	**No:** Go to #8
8. Is the request for a patient ≥21 years of age?	**Yes**: Go to #9	**No**: Go to EPSDT assessment Message: Requests for non-covered services can be considered with individual review under EPSDT.

Approval Criteria		
9. "70" NDC Not Covered (Transaction line states "Non-Rebatable Drugs")	**Yes:** Go to #10	**No:** Go to #12
10. Is the request for an over-the-counter (OTC) product? See types of OTC products currently covered by OHP here: www.orpdl.org	**Yes**: Go to #11	**No:** Pass to RPh. Deny (Non-Rebatable Drug) with message "The drug requested is made by company that does not participate in Medicaid Drug Rebate Program and is therefore not covered"
11. Is there documentation that covered alternatives are not medically appropriate or are unavailable? Note: many OTC products have rebatable or legend alternatives that are covered.	**Yes:** Pass to RPh; Deny and refer non-rebatable products to DMAP for consideration of a rebate-exception. Document reason (e.g., drug shortage, lack of covered alternatives, intolerance/contraindication to alternatives, etc)	**No:** Pass to RPh. Deny (Non-Rebatable Drug) with message "The drug requested is made by company that does not participate in Medicaid Drug Rebate Program and is therefore not covered. Consider switching treatment to a covered alternative."

Approval Criteria		
12. RPh only: “70” NDC Not Covered (Drugs on the Exclusion List) All indications need to be evaluated to see if they are covered and whether they are above the line or below the line.	**Above:** Deny with yesterday’s date (Medically Appropriateness) and use clinical judgment to APPROVE for 1 month starting today to allow time for appeal. Message: “Although the request has been denied for long term use because it is considered medically inappropriate, it has also been APPROVED for one month to allow time for appeal.”	**Below:** Pass to RPh; Deny. Not covered Message: “The treatment for your condition is not a covered service on the Oregon Health Plan.”

EPSDT Assessment		
1. Is the request for a member ≥21 years of age?	**Yes:** Go to Approval Criteria	**No:** Go to #2
2. Is the request for a cosmetic indication, impotency, erectile dysfunction or infertility? These conditions are not covered under the OHP. See state plan full coverage list.	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not covered Message: “The treatment for your condition is not a covered service on the Oregon Health Plan.”
3. Is the request for a funded condition?	**Yes:** Go to #5	**No:** Go to #4
4. 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:** Go to #5	**No:** Pass to RPh. Deny; medical necessity.
5. Is the request for an FDA approved indication?	**Yes:** Go to #7	**No:** Go to #6

EPSDT Assessment		
6. Is there documentation that the requested treatment is supported by guidelines and compendia?	**Yes:** Go to #7 Document guideline, compendia, and/or literature referenced by the provider.	**No:** Pass to RPh. Deny; medical appropriateness. Off-label requests must include supporting literature.
7. Is there documentation that alternative therapies (including covered pharmacologic and non-pharmacologic therapies) provide inadequate treatment, are not medically appropriate, are unavailable, or are inaccessible?	**Yes:** Pass to RPh; Deny; non-covered service and refer to DMAP for secondary evaluation. Message: The requested treatment cannot be approved without secondary evaluation by DMAP. The request has been referred for evaluation under EPSDT.	**No:** Pass to RPh. Deny; medical appropriateness. Document therapies that have been previously tried. Consider switching to a covered alternative if appropriate.

If the DMAP call center notes a drug is often requested for a covered indication, notify Lead Pharmacist so that policy changes can be considered for valid covered diagnoses.

Table 1. Drug categories commonly used for non-covered conditions

Exclusion List		
Drug Code	**Description**	**DMAP Policy**
DCC = 1	Drugs To Treat Impotency/ Erectile Dysfunction	Impotency Not Covered on OHP List, BPH is covered
DCC = B	Fertility Agents	Fertility Treatment Not Covered on OHP List
DCC= F	Weight Loss Drugs	Obesity is a covered condition, but weight loss drugs are not a covered drug class. Case-by-case review for members covered under the EPSDT program allowed.
HIC3= L1C	Hypertrichotic Agents, Systemic/Including Combinations	Cosmetic Indications Not Covered

HIC3= Q6F	Contact Lens Preparations	Cosmetic Indications Not Covered
HIC3=L5B	Sunscreens	Cosmetic Indications Not Covered
HIC3=L5C	Abrasives	Cosmetic Indications Not Covered
HIC3=L7A	Shampoos	Cosmetic Indications Not Covered
HIC3=L8A	Deodorants	Cosmetic Indications Not Covered
HIC3=L8B	Antiperspirants	Cosmetic Indications Not Covered
HIC3=L9A	Topical Agents, Misc	Cosmetic Indications Not Covered
HIC3=L9C	Antimelanin Agents	Cosmetic Indications Not Covered
HIC3=L9D	Topical Hyperpigmentation Agent	Cosmetic Indications Not Covered
HIC3=L9F	Topical Skin Coloring Dye Agent	Cosmetic Indications Not Covered
HIC3=L9I	Topical Cosmetic Agent; Vit A	Cosmetic Indications Not Covered
HIC3=L9J	Hair Growth Reduction Agents	Cosmetic Indications Not Covered
HIC3=Q5C	Topical Hypertrichotic Agents	Cosmetic Indications Not Covered

Table 2. Drugs requiring alternative billing

Exclusion List		
Drug Code	**Description**	**DMAP Policy**
DCC = D	Diagnostics	DME Billing Required
DCC= Y	Ostomy Supplies	DME Billing Required
HIC3= B0P	Inert Gases	DME Billing Required

Table 3. Drugs commonly used for unfunded conditions or OTC drugs that have not been reviewed for coverage under the Oregon Health Plan

Exclusion List		
Drug Code	**Description**	**DMAP Policy**
HIC3=D6C	Alosetron Hcl	IBS Not Funded on OHP List
HIC3=D6E	Tegaserod	IBS Not Funded on OHP List
HIC3=L3P	Topical Antipruritic Agents	Not Covered OTC
HIC3=L4A	Astringents	Not Covered OTC
HIC3=L5A; Except HSN= 002466 (Podophyllin Resin), 006081 (podofilox), 002470 (benzoyl peroxide)	Keratolytics	Not Covered OTC; Warts, Corns/Calluses; Seborrhea Are Not Funded on OHP List

HIC3=L5B	Sunscreens	Not Covered OTC
HIC3=L5C	Abrasives	Not Covered OTC; Acne, Warts, Corns/Callouses; Diaper Rash, Seborrhea Are Not Funded on OHP List
HIC3=L5E	Anti Seborrheic Agents	Seborrhea Not Funded on OHP List
HIC3=L5G	Rosacea Agents, Topical	Rosacea Not Funded on OHP list, some acne severities are Funded
HIC3=L6A; Except HSN = 002577 (coal tar) 002576 002574 036916 002572 (Capsaicin)	Irritants	Not Covered OTC; Seborrhea, Sprains Not Funded on OHP List
HIC3=L7A	Shampoos	Not Covered OTC; Seborrhea, Not Funded on OHP List
HIC3=L9A	Topical Agents, Misc	Not Covered OTC; Warts, Corns/Callouses; Diaper Rash, Seborrhea, are Not Funded on OHP List
HIC3=Q6R, Q6U, Q6D	Antihistamine-Decongestant, Vasoconstrictor and Mast Cell Eye Drops	Allergic Conjunctivitis Not Funded on OHP List
HIC3= U5A, U5B, U5F & S2H plus HSN= 014173	Herbal Supplements “ Natural Anti-Inflammatory Supplements” - Not Including Nutritional Supplements such as: Ensure, Boost, Etc.	Not Covered OTC
HSN=003344	Sulfacetamide Sodium/Sulfur Topical	Seborrhea Not Funded on OHP list

HSN=025510	Rosacea	Rosacea Not Funded on OHP List, some acne severities are funded
TC=93; Except lotions, creams, & ointments	Emollients/Protectants	Not Covered OTC

P&T Review: *12/23; 3/18; 2/23/06*
Implementation: *1/1/24; 4/16/18; 5/1/16; 9/1/06; 1/1/12*