Select Drug Quantity Management

Policy # 00625
Original Effective Date: 01/01/2019
Current Effective Date: 11/11/2024

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.

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Note: Topical Antipruritics coverage criteria (NON-QUANTITY related) are addressed separately in medical policy 00581.

Note: Topical Immunomodulators coverage criteria (NON-QUANTITY related) are addressed separately in medical policy 00524.

Note: Topical Actinic Keratosis Products coverage criteria (NON-QUANTITY related) are addressed separately in medical policy 00579.

Note: Topical Antifungals coverage criteria (NON-QUANTITY related) are addressed separately in medical policy 00527.

Note: Topical Corticosteroids coverage criteria (NON-QUANTITY related) are addressed separately in medical policy 00318.

Note: Topical Anesthetics coverage criteria (NON-QUANTITY related) are addressed separately in medical policy 00580.

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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 quantity override requests for the drugs included in this policy to be **eligible for coverage**** when the requested drug's quantity override criteria are met.

Patient Selection Criteria

Quantity override requests for the drugs included in this policy will be considered when the selected drug's criteria are met:

- **Topical Antipruritics:**

Drugs	Quantity Override per 30 Days	Quantity Override per 90 Days	Timeframe
doxepin 5% cream	90 gm	N/A	30 days
prudoxin 5% cream	90 gm	N/A	30 days
Zonalon®‡ (doxepin) 5% cream	90 gm	N/A	30 days

  - Patient is treating greater than 9% of body surface area (BSA) OR patient requires two, 8 day treatment periods per 30 days.

- **Topical Atopic Dermatitis Products:**

Drugs	Quantity Override per 30 Days	Quantity Override per 90 Days	Timeframe
Elidel®‡ (pimecrolimus) 1% cream	200 gm	600 gm	12 months
pimecrolimus 1% cream	200 gm	600 gm	12 months
Protopic®‡ (tacrolimus) 0.03%, 0.1% ointment	200 gm	600 gm	12 months

tacrolimus 0.03%, 0.1% ointment	200 gm	600 gm	12 months
Eucrisa®‡ (crisaborole) 2% ointment	240 gm	720 gm	12 months

- Patient is treating greater than 9% of BSA OR patient is applying the selected drug more frequently than twice per day.

- **Topical Actinic Keratosis Products:**

Drugs	Quantity Override per 28 Days	Quantity Override per 84 Days	Timeframe
diclofenac 3% gel	100 gm per EACH ADDITIONAL THREE 5 cm x 5 cm sites treated	100 gm per EACH ADDITIONAL THREE 5 cm x 5 cm sites treated	12 months

- Patient is treating MORE than THREE 5 cm x 5 cm actinic keratosis lesions.

- **Topical Antifungals:**

Drugs	Quantity Override per 28 Days	Quantity Override per 84 Days	Timeframe
Mentax®‡ (butenafine) 1% cream	30 gm	N/A	28 days
Loprox®‡ (ciclopirox) 0.77% cream	90 gm	N/A	28 days
ciclopirox 0.77% cream	90 gm	N/A	28 days
ciclodan 0.77% cream	90 gm	N/A	28 days
ciclopirox 0.77% gel	45 gm	N/A	28 days
ciclopirox 0.77% suspension	60 mL	N/A	28 days
clotrimazole 1% cream	45 gm	N/A	28 days
clotrimazole 1% solution	30 mL	N/A	28 days
clotrimazole-betamethasone 1%/0.05% cream	45 gm	N/A	28 days
clotrimazole-betamethasone 1%/0.05% lotion	60 mL	N/A	28 days

econazole 1% cream	85 gm	N/A	28 days
Ecoza™‡ (econazole) 1% foam	70 gm	N/A	28 days
ketoconazole 2% cream	60 gm	N/A	28 days
Extina®‡ (ketoconazole) 2% foam	100 gm	N/A	28 days
ketoconazole 2% foam	100 gm	N/A	28 days
Xolegel®‡ (ketoconazole) 2% gel	45 gm	N/A	28 days
Luzu®‡ (luliconazole) 1% cream	60 gm	N/A	28 days
Naftin®‡ (naftifine) 1%, cream	60 gm	N/A	28 days
naftifine 1%, 2% cream	60 gm	N/A	28 days
Naftin (naftifine) 2% gel	60 gm	N/A	28 days
naftifine 2% gel	60 gm	N/A	28 days
Oxistat®‡ (oxiconazole) 1% cream	60 gm	N/A	28 days
oxiconazole 1% cream	60 gm	N/A	28 days
Oxistat (oxiconazole) 1% lotion	60 mL	N/A	28 days
Ertaczo®‡ (sertaconazole) 2% cream	60 gm	N/A	28 days
Exelderm®‡ (sulconazole) 1% cream	60 gm	N/A	28 days
Exelderm (sulconazole) 1% solution	60 mL	N/A	28 days
nystatin 100,000 units/gm powder	120 gm	N/A	28 days
nystop 100,000 units/gm powder	120 gm	N/A	28 days
nyamyc 100,000 units/gm powder	120 gm	N/A	28 days

nystatin 100,000 units/gm cream	30 gm	N/A	28 days
nystatin 100,000 units/gm ointment	30 gm	N/A	28 days
nystatin-triamcinolone 100,000units/0.1% cream	60 gm	N/A	28 days
nystatin-triamcinolone 100,000units/0.1% ointment	60 gm	N/A	28 days
ANY other topical antifungal product	NO OVERRIDES ALLOWED	NO OVERRIDES ALLOWED	NO OVERRIDES ALLOWED

- Patient is treating greater than 9% of BSA OR patient is treating the condition for longer than 14 days.

- **Topical Anti-inflammatory Products:**

Drugs	Quantity Override	Quantity Override	Timeframe
Clobex®‡ (clobetasol) 0.05% lotion	118 mL per 28 days	N/A	28 days
clobetasol 0.05% lotion	118 mL per 28 days	N/A	28 days
Clobex (clobetasol) 0.05% spray	125 mL per 28 days	N/A	28 days
clobetasol 0.05% spray	125 mL per 28 days	N/A	28 days
Vanos®‡ (fluocinonide) cream 0.1%	180 gm per 30 days	540 gm per 90 days	12 months
fluocinonide 0.1% cream	180 gm per 30 days	540 gm per 90 days	12 months
ANY other topical clobetasol or fluocinonide product	NO OVERRIDES ALLOWED	NO OVERRIDES ALLOWED	NO OVERRIDES ALLOWED

- clobetasol products (lotion and spray ONLY):
  - Patient's condition has not sufficiently improved after the initial two weeks of therapy with the requested product.

- fluocinonide products (0.1% cream ONLY [Vanos, generic]):
  - Patient is treating greater than 8% of BSA OR patient is applying the selected drug more frequently than twice per day.

- **Topical Lidocaine Products:**

Drugs	Quantity Override per 30 Days	Quantity Override per 90 Days	Timeframe
lidocaine 5% ointment	150 gm	N/A	12 months
Xylocaine (lidocaine) 2% jelly	1800 mL	N/A	12 months
lidocaine 2% jelly	1800 mL	N/A	12 months
glydo (lidocaine) 2% jelly	1800 mL	N/A	12 months
lidocaine/prilocaine 2.5%/2.5% cream	30 gm for each instance of criteria	N/A	12 months
ANY other lidocaine or prilocaine topical product	NO OVERRIDES ALLOWED	NO OVERRIDES ALLOWED	NO OVERRIDES ALLOWED

  - lidocaine 5% ointment:
    - Patient is using to produce anesthesia of accessible mucous membranes of the oropharynx greater than 2% of BSA OR patient administers more frequently than two times a day.
  - lidocaine 2% jelly, glydo, Xylocaine:
    - Patient performs self-catheterization on a routine basis.
  - lidocaine 2.5%/prilocaine 2.5% cream:
    - Patient needs topical anesthesia for greater than 12 separate dermal procedures (intravenous cannulation and venipuncture) utilizing 2.5 grams OR 6 separate dermal procedures (intravenous cannulation and venipuncture) utilizing 5 grams.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers quantity override requests for the drugs included in this policy when the patient selection criteria are not met to be **not medically necessary.****

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Background/Overview

Topical Antipruritics/Topical Atopic Dermatitis Products

Doxepin topical cream is indicated for the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus. A thin film of doxepin cream should be applied four times each day with at least a 3 to 4 hour interval between applications. There are no data to establish the safety and effectiveness of doxepin cream when used for greater than 8 days. Chronic use beyond eight days may result in higher systemic levels and should be avoided. Use of doxepin cream for longer than 8 days may result in an increased likelihood of contact sensitization.

Elidel (pimecrolimus cream) and Protopic (tacrolimus ointment) are indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable. Eucrisa (crisaborole) is indicated for topical treatment of mild to moderate atopic dermatitis.

In clinical trials of patients with atopic dermatitis, 75-80% had disease affecting the face and/or neck region. The most common areas of the body affected by atopic dermatitis are the face, chest and back of scalp in infants and young children. In older children and adults, the front of elbows, behind the knees, face, palms of hands and soles of feet are most commonly affected. The head and neck region, upper or lower chest, each leg, or each arm comprise approximately 9% of BSA. References related to the quantity of topical creams and ointments needed to treat the involved BSA of various dermatoses estimate that between 85 - 135 grams of ointment or cream would be needed to cover a 9% BSA region when applying two times daily for one month.

Topical Actinic Keratosis Products

Diclofenac 3%, formerly known under brand name Solaraze®‡ Gel, is applied to lesion areas twice daily. It is to be smoothed onto the affected skin gently. The amount needed depends upon the size of the lesion site. Normally 0.5 gm of gel is used on each 5 cm x 5 cm lesion site. The recommended duration of therapy is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

Topical Antifungals
Topical antifungal products are used to treat a variety of superficial fungal infections (e.g., tinea, candida) diaper dermatitis, and seborrheic dermatitis. Frequency of administration is typically one to two times daily. Duration of treatment varies depending on the fungus being treated, but is most often used for an initial two week period or less. Treatment can last for up to four weeks in some cases if no clinical improvement is seen after two weeks of treatment.

The quantity limits for topical antifungal products supplies a sufficient quantity for each of the topical antifungal products to treat 9% of a patient's BSA when applied up to twice a day for 14 days. For patients treating a larger surface area or for a longer duration than 14 days, additional quantities listed are available through coverage review

Topical Anti-inflammatory Products
Clobetasol lotion and spray are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including moderate-to-severe plaque psoriasis. Clobetasol is a super-high potency topical corticosteroid; therefore, treatment should be limited to 2 consecutive weeks and amounts greater than 50 grams or 50 ml per week should not be used.

Vanos (fluocinonide cream) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including moderate-to-severe plaque psoriasis. Moderate-to-severe psoriasis is typically defined as involvement of more than 5 to 10 percent of the BSA (the entire palmar surface, including fingers, of one hand is approximately 1 percent of the BSA) or involvement of the face, palm or sole, or disease that is otherwise disabling. Patients with more than 5 to 10 percent BSA affected are generally candidates for phototherapy or systemic therapy, since application of topical agents to a large area is not usually practical or acceptable for most patients.

Topical Lidocaine Products
Lidocaine ointment is indicated for production of anesthesia of accessible mucous membranes of the oropharynx. It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites. While there is no frequency of administration listed in the prescribing information, medical literature reports typical administration of two times daily. The initial quantity limit is enough drug to cover 2% of the BSA when applying two times daily for one month.

Xylocaine (lidocaine HCl) 2% Jelly is indicated for 1) prevention and control of pain in procedures involving the male and female urethra, 2) for topical treatment of painful urethritis, 3) and as an anesthetic lubricant for endotracheal intubation (oral and nasal). Prior to catheterization, small volumes of 5 to 10 mL (100 to 200 mg) are usually adequate for lubrication. For surface anesthesia of the female adult urethra, 3 to 5 ml (60 to 100 mg) is instilled into the urethra. No more than 600 mg (30 ml) of lidocaine 2% should be administered in any 12 hour period for any of the listed indications.

For lidocaine jelly and ointment, no overrides are recommended for patients with peripheral or post-herpetic neuralgia, post-traumatic peripheral neuropathy, or peripheral diabetic neuropathy. Cochrane reviewed three trials that utilized lidocaine 8% spray or 5% gel in patients with peripheral herpetic neuralgia (PHN) or post-traumatic peripheral neuropathy, and a fourth trial where lidocaine 5% cream had been applied twice daily for 1 week in 30 patients who had PHN, peripheral diabetic neuropathy, or post-traumatic neuropathy. Based on this review, none of the non-patch lidocaine alternatives can be recommended as therapeutic options for treatment of peripheral neuropathic pain due to the relative absence of data.

Lidocaine and prilocaine cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%), formerly known under brand name EMLA, is indicated as a topical anesthetic for use on normal intact skin for local analgesia of minor procedures such as intravenous cannulation and venipuncture, major dermal procedures such as split thickness skin graft harvesting, and genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia. The amount of cream required for topical anesthesia during a minor dermal procedure, such as intravenous cannulation and venipuncture is 2.5 grams according to prescribing information. The initial covered quantity is enough drug to allow for 6 separate dermal procedures utilizing 5 grams or 12 separate dermal procedures utilizing 2.5 grams.

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 intent of this policy is to prevent stockpiling, misuse, and/or overuse while also allowing appropriate quantities for clinically acceptable and relevant use.

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64. Topical Doxepin Cream Duration Limit. Express Scripts. Updated 5/2017.
65. Topical Products for Atopic Dermatitis Duration Limit. Express Scripts. Updated 4/2017.

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10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. New policy.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. Added the generic for Elidel (pimecrolimus) to the policy for completeness.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2024	Medical Policy Committee review
10/08/2024	Medical Policy Implementation Committee approval. Removed brand Solaraze, brand Loprox 0.77% suspension, brand Lotrisone®‡, brand Naftin 2% cream, brand Naftin 1% gel, and brand EMLA from policy due to products being discontinued. Added generic naftifine 2% gel to policy.

Next Scheduled Review Date: 10/2025

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**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.