



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Topical Corticosteroids – Clobetasol Drug Quantity Management Policy – Per Days
- clobetasol cream 0.05% (generic only)
 - clobetasol emollient cream 0.05% (generic only)
 - clobetasol gel 0.05% (generic only)
 - clobetasol solution 0.05% (generic only)
 - Clobex[®] (clobetasol lotion 0.05%, shampoo 0.05%, and spray 0.05% – Galderma, generic)
 - Clodan[®] (clobetasol shampoo 0.05% – Medimetriks, generic)
 - Clodan[™] Kit (clobetasol shampoo 0.05% and Rehyla[®] Hair & Body Cleanser – Medimetriks)
 - Impeklo[™] (clobetasol lotion 0.05%, metered dose pump – Mylan)
 - Impoyz[®] (clobetasol cream 0.025% – Primus, authorized generic)
 - Olux[®] (clobetasol foam 0.05% – Mylan, generic)
 - Olux[®]-E (clobetasol emollient foam 0.05% – Mylan, generic)
 - Temovate[®] (clobetasol ointment 0.05% – Sandoz, generic)

REVIEW DATE: 04/03/2025

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Clobetasol propionate is a super-high potency corticosteroid. In general, the topical clobetasol products included in this policy are indicated for the relief of the inflammatory and pruritic manifestations of **corticosteroid-responsive dermatoses**, including moderate-to-severe plaque psoriasis.¹⁻¹³

Clobetasol propionate 0.05% emollient cream, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients ≥ 12 years of age.⁵ It also indicated is indicated for the topical treatment of moderate to severe plaque-type psoriasis in patients ≥ 16 years of age.

Clobetasol propionate 0.05% topical solution is indicated for short-term topical treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses of the scalp in patients ≥ 12 years of age.⁴

Clobetasol propionate 0.05% gel is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients ≥ 12 years of age.³

Clobetasol 0.05% lotion (Clobex, generic) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients ≥ 18 years of age.⁶

Clobetasol 0.05% shampoo (Clobex, generic) is indicated for the treatment of moderate to severe forms of scalp psoriasis in patients ≥ 18 years of age.⁷

Clobetasol 0.05% spray (Clobex, generic) is indicated for the treatment of moderate to severe plaque psoriasis affecting up to 20% body surface area (BSA) in patients ≥ 18 years of age.⁸

Clobetasol 0.05% shampoo (Clodan, generic) is indicated for the treatment of moderate to severe forms of scalp psoriasis in patients ≥ 18 years of age.¹¹ Impeklo 0.05% metered dose pump lotion is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, in patients ≥ 18 years of age.¹³

Impoyz 0.025% cream is indicated for the treatment of moderate to severe plaque psoriasis in patients ≥ 18 years of age.¹²

Clobetasol 0.05% foam (Olux, generic) is indicated for the treatment of moderate to severe plaque psoriasis of the scalp and mild to moderate plaque psoriasis of non-scalp regions of the body excluding the face and intertriginous areas in patients ≥ 12 years of age.⁹ Clobetasol 0.05% emollient foam (Olux-E, generic) is indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients ≥ 12 years of age.¹⁰

Clobetasol 0.05% cream and clobetasol 0.05% ointment (Temovate, generic) are indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients ≥ 12 years of age.¹

Dosing/Availability

Most of the topical clobetasol products are applied to the affected area(s) twice daily (BID) and treatment is limited to 2 consecutive weeks. For plaque psoriasis, an additional 2 weeks of treatment may be considered (see below); treatment beyond 4 consecutive weeks is not recommended. For psoriasis of the scalp, clobetasol shampoos are applied once daily (QD), and the total duration of treatment is 4 weeks. For all of the topical clobetasol products, amounts > 50 grams per week should not be used. Coverage will be limited to a quantity sufficient to allow for a 2-week treatment course per 28 days at maximum recommended weekly doses based on available package size. A coverage review is required for additional quantities. Additional dosing details are provided below for completeness. Refer to the quantity limits table for availability information.

In moderate to severe plaque-type psoriasis, clobetasol propionate 0.05% emollient cream (generic only) can be applied to 5% to 10% of the BSA for up to 4 weeks.⁵ When used for > 2 weeks, any additional benefits of extending treatment should be weighed against the risk of hypothalamic pituitary axis (HPA) suppression. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Clobetasol propionate 0.05% topical solution (generic only) is applied to the affected scalp area(s) BID.⁴ Treatment beyond 2 consecutive weeks is not recommended.

Clobetasol propionate 0.05% gel (generic only) is applied to the affected area(s) BID.³ Treatment beyond 2 consecutive weeks is not recommended.

Clobetasol 0.05% lotion (Clobex, generic) is applied to the affected area(s) BID.⁶ Treatment beyond 2 consecutive weeks is not recommended. For moderate to severe plaque psoriasis, treatment may be extended for an additional 2 weeks for localized lesions (< 10% body surface area) that have not sufficiently improved after the initial 2-week treatment. The total dosage should not exceed 50 grams (50 mL or 1.75 fl. oz.) per week.

Clobetasol 0.05% shampoo (Clobex, generic) is applied once daily (QD) to the affected area.⁷ Treatment should be limited to 4 consecutive weeks.

Clobetasol 0.05% spray (Clobex, generic) is applied to the affected area(s) BID.⁸ Treatment beyond 2 weeks should be limited to localized lesions of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment with clobetasol 0.05% spray. The total dose should not exceed 50 grams (59 mL or 2 fluid ounces) per week. No more than 26 sprays per application or 52 sprays per day should be used.

Clobetasol 0.05% shampoo (Clodan, generic) is applied QD to the affected area(s).¹¹ Treatment should be limited to 4 consecutive weeks. The total dosage should not exceed 50 gram (50 mL or 1.75 fluid ounces) per week.

Impeklo 0.05% metered-dose pump lotion is applied to the affected skin area(s) BID.¹³ No more than 10 pump actuations per application BID or 20 pump actuations per day for > 7 days is recommended. Treatment should be limited to 2 consecutive weeks for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and up to 2 additional weeks in localized lesions (< 10% body surface area) of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment.

Impoyz 0.025% cream is applied to the affected skin area(s) BID daily for up to 2 consecutive weeks.¹² Treatment beyond 2 consecutive weeks is not recommended.

Clobetasol 0.05% foam (Olux, generic) is applied as a thin layer to the affected skin area(s) BID.⁹ Treatment beyond 2 consecutive weeks is not recommended.

Clobetasol 0.05% emollient foam (Olux-E, generic) is applied to the affected area(s) BID, morning and evening, for up to 2 consecutive weeks.¹⁰ Treatment beyond 2 consecutive weeks is not recommended.

Clobetasol 0.05% cream and ointment (Temovate, generic) are applied to the affected area(s) twice daily, treatment should be limited to 2 consecutive weeks.^{1,2}

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of topical clobetasol products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Package Size	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
clobetasol emollient cream 0.05% (0.5 mg/gram) [generic only]	15 gram tube 30 gram tube 45 gram tube (discontinued) 60 gram tube	120 grams	360 grams
clobetasol gel 0.05% (generic only) [0.5 mg/gram]	15 gram tube 30 gram tube 60 gram tube	120 grams	360 grams

clobetasol solution 0.05% (generic only) [0.5 mg/gram]	25 mL bottle 50 mL bottle	100 mL	300 mL
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Drug Quantity Limits (continued)

Product	Package Size	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Clobex [®] (clobetasol lotion 0.05%, generic) [0.5 mg/gram]	59 mL bottle (2 fluid ounces) 118 mL bottle (4 fluid ounces)	118 mL	354 mL
Clobex [®] (clobetasol shampoo 0.05%, generic) [0.5 mg/gram]	118 mL bottle	236 mL	708 mL
Clobex [®] (clobetasol spray 0.05%, generic) [0.5 mg/gram]	59 mL bottle (2 fluid ounces) 125 mL bottle (4.25 fluid ounces)	125 mL	375 mL
Clodan [™] (clobetasol shampoo 0.05%, generic) [0.5 mg/gram]	118 mL bottle (4 fluid ounces)	236 mL	708 mL
Clodan [™] Kit (clobetasol shampoo 0.05% and Rehyla [®] Hair & Body Cleanser) [0.5 mg/gram]	118 mL bottle (4 fluid ounces)	2 kits (236 mL)	6 kits (708 mL)
Impeklo [™] (clobetasol lotion 0.05%, metered dose pump) [discontinued]	68 gram bottle (0.15 mg/0.30 g per pump; 138 pumps per bottle)	136 grams	408 grams
Impoyz [™] (clobetasol cream 0.025%, authorized generic) [0.25 mg/gram]	100 gram tube	120 grams	360 grams
Olux [®] (clobetasol foam 0.05%, generic) [0.5 mg/gram]	50 gram can 100 gram can	100 grams	300 grams
Olux [®] -E (clobetasol emollient foam 0.05%, generic) [0.5 mg/gram]	50 gram can 100 gram can	100 grams	300 grams
clobetasol cream 0.05%, generic (0.5 mg/gram) [generic only]	15 gram tube 30 gram tube 45 gram tube 60 gram tube	120 grams	360 grams
Temovate [®] (clobetasol ointment 0.05%, generic) [0.5 mg/gram] {brand discontinued}	15 gram tube 30 gram tube (generic only) 45 gram tube (generic only) 60 gram tube (generic only)	120 grams	360 grams

Topical Corticosteroids - Clobetasol Drug Quantity Management Policy - Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Approval of additional quantities of the topical clobetasol products below is/are considered medically necessary if the **patient is using the product for steroid-responsive dermatoses** AND meets one of the following criteria:

Clobetasol cream, clobetasol emollient foam (Olux-E, generic), clobetasol foam (Olux, generic), clobetasol gel, clobetasol ointment (Temovate, generic), clobetasol shampoo (Clodan, Clodan Kit, Clobex, generic), clobetasol solution, clobetasol cream (Impoyz, authorized generic).

No overrides recommended.

Clobetasol emollient cream (generic)

1. If the patient requires an additional 2 weeks of treatment, approve a one-time override for an additional 120 grams at retail or home delivery.

Note: At retail, the approval quantity should be the number of grams of clobetasol emollient cream the patient has received in the past 28 days plus 120 grams. At home delivery, the approval quantity should be the number of grams of clobetasol emollient cream the patient has received in the past 84 days plus 120 grams.

Clobetasol lotion (Clobex, generic)

1. If the patient requires an additional 2 weeks of treatment, approve a one-time override for an additional 118 mL at retail or home delivery.

Note: At retail, the approval quantity should be the number of mLs of clobetasol lotion the patient has received in the past 28 days plus 118 mL. At home delivery, the approval quantity should be the number of mLs of clobetasol lotion the patient has received in the past 84 days plus 118 mLs.

Clobetasol spray (Clobex, generic)

1. If the patient requires an additional 2 weeks of treatment, approve a one-time override for an additional 125 mL at retail or home delivery.

Note: At retail, the approval quantity should be the number of mLs of clobetasol spray the patient has received in the past 28 days plus 125 mL. At home delivery, the approval quantity should be the number of mLs of clobetasol spray the patient has received in the past 84 days plus 125 mLs.

Impeklo lotion

1. If the patient requires an additional 2 weeks of treatment, approve a one-time override for an additional 138 grams at retail or home delivery.

Note: At retail, the approval quantity should be the number of grams of Impeklo lotion the patient has received in the past 28 days plus 138 grams. At home

delivery, the approval quantity should be the number of grams of Impeklo lotion the patient has received in the past 84 days plus 138 grams.

EXCLUSIONS

Approval of additional quantities of the topical clobetasol products is NOT considered medically necessary in the following situations:

1. No overrides are recommended for use in compounded formulations.

REFERENCES

1. Clobetasol cream 0.05% [prescribing information]. Bridgewater, NJ: Amneal; December 2023.
2. Clobetasol ointment 0.05% [prescribing information]. Baltimore, MD: Lupin; August 2018.
3. Clobetasol gel 0.05% [prescribing information]. Melville, NY: E. Fougera; September 2020.
4. Clobetasol topical solution 0.5% [prescribing information]. Melville, NY: E. Fougera; March 2024.
5. Clobetasol emollient cream 0.05% [prescribing information]. Melville, NY: E. Fougera; July 2021.
6. Clobex® lotion 0.05% [prescribing information]. Fort Worth, TX: Galderma; February 2018.
7. Clobex® shampoo 0.05% [prescribing information]. Fort Worth, TX: Galderma; October 2024.
8. Clobex® spray 0.05% [prescribing information]. Fort Worth, TX: Galderma; October 2024.
9. Olux® foam 0.05% [prescribing information]. Morgantown, WV: Mylan; April 2018.
10. Olux® E foam 0.05% [prescribing information]. Morgantown, WV: Mylan; May 2018.
11. Clodan® shampoo 0.05% [prescribing information]. Fairfield, NJ: Medimetriks; November 2023.
12. Impoyz® cream 0.025% [prescribing information]. Scottsdale, AZ: Primus; January 2024.
13. Impeklo™ lotion 0.5% [prescribing information]. Morgantown, WV: Mylan; May 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p> <p>Clobetasol emollient cream (generic). Override criteria updated to state: "If the patient requires an additional 2 weeks of treatment, approve a one-time override for 120 grams at retail or home delivery." Previously, the same override applied, but was worded "If the condition has not sufficiently improved after the initial 2 weeks of treatment with clobetasol emollient cream, approve a one-time override for an additional supply of up to 120 grams to allow for a total treatment period of up to 4 consecutive weeks (total quantity 240 grams/28 days)."</p> <p>Clobetasol lotion (Clobex, generic). Override criteria updated to state: "If the patient requires an additional 2 weeks of treatment, approve a one-time override for 118 mL at retail or home delivery." Previously, the same override applied, but was worded "If the condition has not sufficiently improved after the initial 2 weeks of treatment with clobetasol lotion, approve a one-time override for an additional supply of up to 118 mL to allow for a total treatment period of up to 4 consecutive weeks (total quantity 236 mL/28 days)."</p>	04/19/2023

	<p>Clobetasol spray (Clobex, generic). Override criteria updated to state: "If the patient requires an additional 2 weeks of treatment, approve a one-time override for 125 mL at retail or home delivery." Previously, the same override applied, but was worded "If the condition has not sufficiently improved after the initial 2 weeks of treatment with clobetasol spray, approve a one-time override for an additional supply of up to 125 mL to allow for a total treatment period of up to 4 consecutive weeks (total quantity 250 mL/28 days)."</p> <p>Impeklo lotion. Override criteria updated to state: "If the patient requires an additional 2 weeks of treatment, approve a one-time override for 138 grams at retail or home delivery." Previously, the same override applied, but was worded "If the condition has not sufficiently improved after the initial 2 weeks of treatment with Impeklo lotion, approve a one-time override for an additional supply of up to 138 grams to allow for a total treatment period of up to 4 consecutive weeks (total quantity 276 grams/28 days)."</p>	
Annual Revision	No criteria changes.	04/30/2024
Annual Revision	<p>Policy statement was updated to note that "one-time" approvals are provided for 30 days in duration.</p> <p>Brand Temovate 0.05% cream was removed from the policy (obsolete).</p> <p>Clobetasol 0.025% cream, an authorized generic to Impoyz, was added to the policy. The same quantity limits apply to clobetasol 0.025% cream as have previously applied to brand Impoyz. No clinical overrides apply.</p> <p>Clobetasol emollient cream (generic), clobetasol lotion (Clobex, generic), clobetasol spray (Clobex, generic), Impeklo lotion: Notes were added to the override criteria to provide instructions on how to calculate approval quantities.</p>	04/03/2025

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