



## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Topical Corticosteroids – Clobetasol Drug Quantity Management Policy – Per Days
- clobetasol emollient cream 0.05% (generic only)
  - clobetasol gel 0.05% (generic only)
  - clobetasol solution 0.05% (generic only)
  - Clobex<sup>®</sup> (clobetasol lotion 0.05%, shampoo 0.05%, and spray 0.05% – Gladerma, generic)
  - Clodan<sup>™</sup> (clobetasol shampoo 0.05% – Medimetriks, generic)
  - Clodan<sup>™</sup> Kit (clobetasol shampoo 0.05% and Rehyla<sup>®</sup> Hair & Body Cleanser – Medimetriks)
  - Impeklo<sup>™</sup> (clobetasol lotion 0.05%, metered dose pump – Mylan)
  - Impoyz<sup>™</sup> (clobetasol cream 0.025% – Promius)
  - Olux<sup>®</sup> (clobetasol foam 0.05% – Mylan, generic)
  - Olux<sup>®</sup>-E (clobetasol emollient foam 0.05% – Mylan Pharmaceuticals, generic)
  - Temovate<sup>®</sup> (clobetasol cream 0.05% and ointment 0.05% – PharmaDerm, generic)

**REVIEW DATE:** 04/19/2023

### INSTRUCTIONS FOR USE

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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.<sup>1-14</sup>

Clobetasol propionate 0.05% emollient cream, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients  $\geq$  12 years of age.<sup>5</sup> It also indicated is indicated for the topical treatment of moderate to severe plaque-type psoriasis in patients  $\geq$  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  $\geq$  12 years of age.<sup>4</sup> Clobetasol propionate 0.05% gel is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients  $\geq$  12 years of age.<sup>3</sup>

Clobetasol 0.05% lotion (Clobex, generic) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients  $\geq$  18 years of age.<sup>6</sup> Clobetasol 0.05% shampoo (Clobex, generic) is indicated for the treatment of moderate to severe forms of scalp psoriasis in patients  $\geq$  18 years of age.<sup>7</sup> 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  $\geq$  18 years of age.<sup>8</sup>

Clobetasol 0.05% shampoo (Clodan, generic) is indicated for the treatment of moderate to severe forms of scalp psoriasis in patients  $\geq$  18 years of age.<sup>11</sup>

Impeklo 0.05% metered dose pump lotion is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, in patients  $\geq$  18 years of age.<sup>13</sup>

Impoyz 0.025% cream is indicated for the treatment of moderate to severe plaque psoriasis in patients  $\geq$  18 years of age.<sup>12</sup>

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  $\geq$  12 years of age.<sup>9</sup> Clobetasol 0.05% emollient foam (Olux-E, generic), clobetasol 0.05% cream (Temovate, generic), and clobetasol 0.05% ointment (Temovate, generic) are indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients  $\geq$  12 years of age.<sup>1,10</sup>

### **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 and availability are provided below for completeness.

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.<sup>5</sup> 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% emollient cream is supplied in 15 gram, 30 gram, 45 gram, and 60 gram tubes. Each gram of emollient cream contains 0.5 mg of clobetasol (0.05%).

Clobetasol propionate 0.05% topical solution (generic only) is applied to the affected scalp area(s) BID.<sup>4</sup> Treatment beyond 2 consecutive weeks is not recommended. Clobetasol propionate 0.05% topical solution is supplied as 25 mL and 50 mL squeeze bottles.

Clobetasol propionate 0.05% gel (generic only) is applied to the affected area(s) BID.<sup>3</sup> Treatment beyond 2 consecutive weeks is not recommended. Clobetasol propionate 0.05% gel is available as 15 gram, 30 gram, and 60 gram tubes. Each gram of gel contains 0.5 mg of clobetasol (0.05%).

Clobetasol 0.05% lotion (Clobex, generic) is applied to the affected area(s) BID.<sup>6</sup> 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% lotion (Clobex, generic) is supplied as bottles of 59 mL (2 fluid ounces) and 118 mL (4 fluid ounces). Each gram of 0.05% lotion contains 0.5 mg of clobetasol (0.05%).

Clobetasol 0.05% shampoo (Clobex, generic) is applied once daily (QD) to the affected area.<sup>7</sup> Treatment should be limited to 4 consecutive weeks. Clobetasol shampoo is supplied in 118 mL bottles (4 fluid ounces), each gram of shampoo contains 0.5 mg of clobetasol (0.05%).

Clobetasol 0.05% spray (Clobex, generic) is applied to the affected area(s) BID.<sup>8</sup> 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% spray is supplied in bottles of 59 mL (2 fluid ounces) and 125 mL (4.25 fluid ounces). Each gram of spray contains 0.5 mg of clobetasol (0.05%).

Clobetasol 0.05% shampoo (Clodan, generic) is applied QD to the affected area(s).<sup>11</sup> 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. Clobetasol 0.05% shampoo is supplied in 118 mL (4 fluid ounces) bottles. Each gram of

shampoo contains 0.5 mg of clobetasol (0.05%). Clobetasol shampoo is also part of the Clodan Kit which contains one, 118 mL (4 fluid ounces) bottle of clobetasol 0.05% shampoo and Rehya<sup>®</sup> Hair & Body Cleanser.

Impeklo 0.05% metered-dose pump lotion is applied to the affected skin area(s) BID.<sup>13</sup> 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. Impeklo is supplied as a 0.05% metered dose pump lotion, each pump actuation delivers 0.15 mg of clobetasol propionate in 0.30 grams of lotion. The metered-dose pump is capable of dispensing not less than 138 actuations to deliver not less than 41.4 grams of lotion. One metered dose pump contains 68 grams lotion.

Impoyz 0.025% cream is applied to the affected skin area(s) BID daily for up to 2 consecutive weeks.<sup>12</sup> Treatment beyond 2 consecutive weeks is not recommended. Impoyz is supplied as a 0.025% cream in 60 gram and 100 gram aluminum tubes, each gram of cream contains 0.25 mg of clobetasol (0.25%).

Clobetasol 0.05% foam (Olux, generic) is applied as a thin layer to the affected skin area(s) BID.<sup>9</sup> Treatment beyond 2 consecutive weeks is not recommended. Clobetasol foam is supplied in 50 gram and 100 gram cans. Each gram of foam contains 0.5 mg of clobetasol (0.05%).

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.<sup>10</sup> Treatment beyond 2 consecutive weeks is not recommended. Clobetasol 0.05% emollient foam is supplied as 50 gram and 100 gram cans. Each gram of foam contains 0.5 mg of clobetasol (0.05%).

Clobetasol 0.05% cream (Temovate, generic) and ointment (Temovate, generic) are applied to the affected area(s) twice daily, treatment should be limited to 2 consecutive weeks.<sup>1,2</sup> The cream is supplied in 30 gram and 60 gram tubes. The ointment is supplied in 15 gram, 30 gram, 45 gram, and 60 gram tubes. Each gram of cream or ointment contains 50 mg of clobetasol (0.05%).

## **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.

## 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 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
Clobex <sup>®</sup> (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 <sup>®</sup> (clobetasol shampoo 0.05%, generic) [0.5 mg/gram]	118 mL bottle	236 mL	708 mL
Clobex <sup>®</sup> (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 <sup>™</sup> (clobetasol shampoo 0.05%, generic) [0.5 mg/gram]	118 mL bottle (4 fluid ounces)	236 mL	708 mL
Clodan <sup>™</sup> Kit (clobetasol shampoo 0.05% and Rehyla <sup>®</sup> Hair & Body Cleanser) [0.5 mg/gram]	118 mL bottle (4 fluid ounces)	236 mL (2 kits)	708 mL (6 kits)
Impeklo <sup>™</sup> (clobetasol lotion 0.05%, metered dose pump)	68 gram bottle (0.15 mg/0.30 g per pump; 138 pumps per bottle)	136 grams	408 grams
Impoyz <sup>™</sup> (clobetasol cream 0.025%) [0.25 mg/gram]	60 gram tube 100 gram tube	120 grams	360 grams
Olux <sup>®</sup> (clobetasol foam 0.05%, generic) [0.5 mg/gram]	50 gram can 100 gram can	100 grams	300 grams
Olux <sup>®</sup> -E (clobetasol emollient foam 0.05%, generic) [0.5 mg/gram]	50 gram can 100 gram can	100 grams	300 grams
Temovate <sup>®</sup> (clobetasol cream 0.05%) [0.5 mg/gram]	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]	15 gram tube 30 gram tube 45 gram tube 60 gram tube	120 grams	360 grams
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**Topical Corticosteroids – Clobetasol Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met.**

**CRITERIA**

Approval of additional quantities of the topical clobetasol products below is recommended if the patient is using the product for steroid-responsive dermatoses and meets one of the following criteria:

Clobetasol cream (Temovate, generic), 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, Impoyz.

No exceptions.

Clobetasol emollient cream (generic)

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

Clobetasol lotion (Clobex, generic)

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

Clobetasol spray (Clobex, generic)

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

Impeklo lotion

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

**CONDITIONS NOT COVERED**

**Any other exception is considered not medically necessary, including the following (this list may not be all inclusive):**

1. For use in compounded formulations.

## REFERENCES

1. Clobetasol cream 0.05% [prescribing information]. Bridgewater, NJ: Amneal; December 2022.
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; November 2019.
5. Clobetasol emollient cream 0.05% [prescribing information]. Melville, NY: E. Fougera; July 2021.
6. Clobex<sup>®</sup> lotion 0.05% [prescribing information]. Fort Worth, TX: Galderma; February 2018.
7. Clobex<sup>®</sup> shampoo 0.05% [prescribing information]. Fort Worth, TX: Galderma; January 2023.
8. Clobex<sup>®</sup> spray 0.05% [prescribing information]. Fort Worth, TX: Galderma; December 2018.
9. Olux<sup>®</sup> foam 0.05% [prescribing information]. Morgantown, WV: Mylan; April 2018.
10. Olux<sup>®</sup> E foam 0.05% [prescribing information]. Morgantown, WV: Mylan; May 2018.
11. Clodan<sup>™</sup> shampoo 0.05% [prescribing information]. Fairfield, NJ: Medimetriks; December 2022.
12. Impoyz<sup>™</sup> cream 0.025% [prescribing information]. Princeton, NJ: Promius; November 2017.
13. Impeklo lotion 0.5% [prescribing information]. Morgantown, WV: Mylan; May 2020.
14. Nelson A, Miller A, Fleischer A, Balkrishnan R, Feldman S. How much of a topical agent should be prescribed for children of different sizes? *J Derm Treat.* 2006; 17:224-228.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p>Added Clodan Kit with no overrides.</p> <p><b>Impeklo metered dose pump lotion.</b> Maximum per 28 days updated to 138 grams. Override criteria were updated to allow for an additional supply of 138 grams (276 grams/28 days). Previously approved 136 grams (272 grams/28 days).</p>	03/23/2022
Annual Revision	<p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p> <p><b>Clobetasol emollient cream (generic).</b> 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><b>Clobetasol lotion (Clobex, generic).</b> 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> <p><b>Clobetasol spray (Clobex, generic).</b> 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</p>	04/19/2023

	<p>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><b>Impeklo lotion.</b> 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>	
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