

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[®] (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% – Promius)
 - Olux[®] (clobetasol foam 0.05% – Mylan, generic)
 - Olux[®]-E (clobetasol emollient foam 0.05% – Mylan Pharmaceuticals, generic)
 - Temovate[®] (clobetasol cream 0.05% and ointment 0.05% – PharmaDerm, generic)

REVIEW DATE: 03/23/2022

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.

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.⁴ 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.³ 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.²

Clobex 0.05% lotion (generic) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients ≥ 18 years of age.⁵ Clobex 0.05% shampoo (generic) is indicated for the treatment of moderate to severe forms of scalp psoriasis in patients ≥ 18 years of age.⁶ Clobex 0.05% spray (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.⁷

Clodan 0.05% shampoo (generic) is indicated for the treatment of moderate to severe forms of scalp psoriasis in patients ≥ 18 years of age.¹⁰

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.¹²

Impoyz 0.025% cream is indicated for the treatment of moderate to severe plaque psoriasis in patients ≥ 18 years of age.¹¹

Olux 0.05% foam (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.⁸ Olux-E 0.05% emollient foam (generic), Temovate 0.05% cream (generic), and Temovate 0.05% ointment (generic) are indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients ≥ 12 years of age.^{1,9}

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 can be applied to 5% to 10% of the BSA for up to 4 weeks.⁴ 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 1 gram of emollient cream contains 0.5 mg of clobetasol (0.05% [0.5 mg/1 gram]).

Clobetasol propionate 0.05% topical solution is applied to the affected scalp area(s) BID.³ 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 is applied to the affected area(s) BID.² 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 1 gram of gel contains 0.5 mg of clobetasol (0.05% [0.5 mg/1 gram]).

Clobex 0.05% lotion is applied to the affected area(s) BID.⁵ 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 g (50 mL or 1.75 fl. oz.) per week. Clobex 0.05% lotion is supplied as bottles of 2 fl. oz./59 mL and 4 fl. oz./118 mL. Each 1 gram of Clobex 0.05% lotion contains 0.5 mg of clobetasol (0.05% [0.5 mg/1 gram]).

Clobex 0.05% shampoo is applied once daily (QD) to the affected area.⁶ Treatment should be limited to 4 consecutive weeks. Clobex shampoo is supplied in 118 mL bottles (4 fl. oz), each 1 gram of shampoo contains 0.5 mg of clobetasol (0.05% [0.5 mg/1 gram]).

Clobex 0.05% spray is applied to the affected area(s) BID.⁷ 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 Clobex 0.05% spray. The total dose should not exceed 50 g (59 mL or 2 fluid ounces) per week. No more than 26 sprays per application or 52 sprays per day should be used. Clobex 0.05% spray is supplied in bottles of 2 fl. oz./59 mL and 4.25 fl. oz./125 mL. Each 1 gram of spray contains 0.5 mg of clobetasol (0.05% [0.5 mg/1 gram]).

Clodan 0.05% shampoo is applied QD to the affected area(s).¹⁰ Treatment should be limited to 4 consecutive weeks. The total dosage should not exceed 50 g (50 mL or 1.75 fl. oz.) per week. Clodan 0.05% shampoo is supplied in 4 fl. oz (118 mL) bottles, each 1 gram of shampoo contains 0.5 mg of clobetasol (0.05%; 0.5 mg/1 gram). Clodan shampoo is also part of the Clodan Kit which contains one, 4-fl. oz. (118 mL) bottle of Clodan shampoo and Rehyla[®] Hair & Body Cleanser.

Impeklo 0.05% metered-dose pump lotion is applied to the affected skin area(s) BID.¹² 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 g of lotion. The metered-dose pump is capable of dispensing not less than 138 actuations to deliver not less than 41.4 g of lotion. One metered dose pump contains 68 g lotion.

Impoyz 0.025% cream is applied to the affected skin area(s) BID daily for up to 2 consecutive weeks.¹¹ Treatment beyond 2 consecutive weeks is not recommended. Impoyz is supplied as a 0.025% cream in 60 gram and 112 gram aluminum tubes, each 1 gram of cream contains 0.25 mg of clobetasol (0.25 mg/1 gram).

Olux 0.05% foam is applied as a thin layer to the affected skin area(s) BID.⁸ Treatment beyond 2 consecutive weeks is not recommended. Olux foam is supplied in 50 gram and 100 gram cans, each 1 gram of foam contains 0.5 mg of clobetasol (0.05% [0.5 mg/gram]).

Olux-E 0.05% emollient foam is applied to the affected area(s) BID, morning and evening, for up to 2 consecutive weeks.⁹ Treatment beyond 2 consecutive weeks is not recommended. Olux-E 0.05% emollient foam is supplied as 50 gram and 100 gram cans, each 1 gram of foam contains 0.5 mg of clobetasol (0.05% [0.5 mg/gram]).

Temovate 0.05% cream and ointment are applied to the affected area(s) twice daily, treatment should be limited to 2 consecutive weeks.¹ Temovate cream is supplied in 30 gram and 60 gram tubes. Temovate ointment is supplied in 15 gram and 30 gram tubes. Each 1 gram of cream or ointment contains 50 mg of clobetasol (0.05% [0.5 mg/gram]).

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 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Package Size	Maximum Quantity per 28 Days
clobetasol emollient cream 0.05% (generic only)	15 gram tube (0.5 mg/gram)	120 grams
	30 gram tube (0.5 mg/gram)	120 grams
	45 gram tube (0.5 mg/gram)	120 grams
	60 gram tube (0.5 mg/gram)	120 grams
clobetasol gel 0.05% (generic only)	15 gram tube (0.5 mg/gram)	120 grams
	30 gram tube (0.5 mg/gram)	120 grams
	45 gram tube (0.5 mg/gram)	120 grams
clobetasol solution 0.05% (generic only)	25 mL bottle (0.5 mg/gram)	100 mL
	30 mL bottle (0.5 mg/gram)	
Clobex [®] lotion (clobetasol lotion 0.05%, generic)	59 mL bottle (2 fl. oz./59 mL; 0.5 mg/1 gram)	118 mL
	118 mL bottle (4 fl. oz./118 mL; 0.5 mg/1 gram)	
Clobex [®] shampoo (clobetasol shampoo 0.05%, generic)	118 mL bottle (0.5 mg/1 gram)	236 mL
Clobex [®] spray (clobetasol spray 0.05%, generic)	59 mL bottle (2 fl. oz./ 59 mL; 0.5 mg/1 gram)	125 mL
	125 mL bottle (4.25 fl. oz./125 mL; 0.5 mg/1 gram)	125 mL
Clodan [™] (clobetasol shampoo 0.05%, generic)	118 mL bottle (4 fl. oz/118 mL; 0.5 mg/1 gram)	236 mL
Clodan [™] Kit (clobetasol shampoo 0.05% and Rehyla [®] Hair & Body Cleanser)	118 mL bottle (4 fl. oz/118 mL; 0.5 mg/1 gram)	236 mL
Impeklo [™] (clobetasol lotion 0.05%, metered dose pump)	69 gram bottle (0.15 mg/0.30 g per pump)	138 grams
Impoyz [™] (clobetasol cream 0.025%)	60 gram tube (0.25 mg/1 gram)	120 grams
	112 gram tube	120 grams
Olux [®] (clobetasol foam 0.05%, generic)	50 gram can (0.5 mg/1 gram)	100 grams
	100 gram can (0.5 mg/1 gram)	
Olux [®] -E (clobetasol emollient foam 0.05%, generic)	50 gram can (0.5 mg/1 gram)	100 grams
	100 gram can (0.5 mg/1 gram)	
Temovate [®] cream (clobetasol cream 0.05%)	30 gram tubes (0.5 mg/1 gram)	120 grams
	60 gram tubes (0.5 mg/1 gram)	
Temovate [®] ointment (clobetasol ointment 0.05%, generic)	30 gram tubes (0.5 mg/1 gram)	120 grams
	15 gram tubes (0.5 mg/1 gram)	

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 overrides.

Clobetasol emollient cream

1. 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).

Clobex lotion (generic)

1. 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).

Clobex spray (generic)

1. 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).

Impeklo lotion, metered dose pump

1. 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).

EXCLUSIONS

Approval of additional quantities of the topical clobetasol products is NOT recommended in the following situations:

1. No overrides are recommended for use in compounded formulations.
2. No overrides are recommended for any non-FDA-approved indications.

REFERENCES

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2. clobetasol gel 0.05% [prescribing information]. Melville, NY: E. Fougera; August 2012.
3. Clobetasol topical solution 0.5% [prescribing information]. Parsippany, NJ: Actavis; August 2019.
4. Clobetasol emollient cream 0.05% [prescribing information]. Melville, NY: Fougera; July 2021.
5. Clobex[®] lotion 0.05% [prescribing information]. Forth Worth, TX: Galderma.; February 2018.
6. Clobex[®] shampoo 0.05% [prescribing information]. Forth Worth, TX: Galderma.; October 2021.
7. Clobex[®] spray 0.05% [prescribing information]. Forth Worth, TX: Galderma; January 2019.
8. Olux[®] foam 0.05% [prescribing information]. Morgantown, WV: Mylan; April 2018.
9. Olux[®] E foam 0.05% [prescribing information]. Morgantown, WV: Mylan; May 2018.
10. Clodan[™] shampoo 0.05% [prescribing information]. Fairfield, NJ: Medimetriks; December 2017.
11. Impoyz cream 0.025% [prescribing information]. Princeton, NJ: Promius; November 2017.
12. Impeklo lotion 0.5% [prescribing information]. Morgantown, WV: Mylan; May 2020.
13. 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.
14. Clodan[™] Kit [prescribing information]. Fairfield, NJ: Medimetriks; December 2021.