

# **DRUG QUANTITY MANAGEMENT POLICY – PER DAYS**

POLICY:

Topical Antibiotics for Acne – Clindamycin DQM Policy – Per Days

- Cleocin T<sup>®</sup> (clindamycin phosphate 1% topical lotion Pfizer, generic)
- Clindagel<sup>®</sup> (clindamycin 1% topical gel Bausch Health, generic)
- Clindamycin 1% topical solution (generic only [to formerly available Cleocin T<sup>®</sup> solution])
- Clindamycin 1% topical gel (generic only [to formerly available Cleocin T<sup>®</sup> gel])
- Evoclin<sup>®</sup> (clindamycin phosphate 1% topical foam Mylan, generic)

### **Review Date:** 02/07/2025

#### **INSTRUCTIONS FOR USE**

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

### CIGNA NATIONAL FORMULARY COVERAGE:

#### **O**VERVIEW

The topical clindamycin products are indicated for the treatment of **acne vulgaris**.<sup>1</sup>

### **Dosing/Availability**

Clindamycin topical gel, lotion, and solution (Cleocin T, generic) may be applied twice daily to the affected area.<sup>1</sup> Clindamycin 1% topical gel (generic only) is supplied as a 30 g and 60 g tube; clindamycin 1% topical lotion (Cleocin T, generic)

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is supplied as a 60 mL bottle. Clindamycin 1% topical solution (Cleocin T, generic) is supplied as 30 mL and 60 mL (generic only) bottles and a carton of 60 single-use pledget applicators (10 mg/mL) [generic only].

Clindamycin topical gel (Clindagel, generic) may be applied once daily to the affected area.<sup>2</sup> Clindamycin 1% gel (Clindagel, generic) is supplied as a 75 mL bottle.

Clindamycin foam (Evoclin, generic) is applied once daily to affected areas; enough should be applied to cover the entire affected area.<sup>3</sup> Clindamycin 1% foam (Evoclin, generic) is supplied as a 50 g or 100 g aerosol can.

# **Application Information**

For topical product application, a standard measure, the finger-tip unit (FTU), is often used.<sup>4</sup> One FTU is the amount of product that is squeezed out of a standard tube along an adult's fingertip. One FTU is equivalent to approximately 0.5 g and provides enough product to treat an area of skin that is twice the size of one adult hand, or approximately 2% of an adult's total body surface area (BSA). Based on the FTU method, 120 grams provides enough product to cover approximately 8% of the patient's BSA when applying two times daily for 30 days.

The most common areas for acne breakouts are the face, chest, shoulders and back.<sup>5</sup> Typically, acne does not cover the entire surface area of the face, chest, shoulders and back, but appears in selected areas of each. A quantity of 120 mL or 120 gram of topical clindamycin would be enough to treat the entire face, shoulders, or upper chest.

# **POLICY STATEMENT**

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse use of topical clindamycin 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.

Product	Package Size	Retail Maximum Quantity per 30 Days	Home Delivery Maximum Quantity per 90 Days
Clindamycin 1% topical gel (generic only to formerly available Cleocin T <sup>®</sup> gel)	30 gram tube	120 grams*	360 grams <sup><math>\Omega</math></sup>
	60 gram tube		
Cleocin T <sup>®</sup> (clindamycin 1% topical lotion, generic)	60 mL bottle	120 mL*	360 mL <sup>Ω</sup>
Clindamycin 1% topical	30 mL bottle	120 mL*	360 mL <sup>Ω</sup>
solution	60 mL bottle		

# Drug Quantity Limits

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(generic only to formerly available Cleocin T <sup>®</sup> solution)	10 mg/mL single-use pledget applicators (Carton of 60)		
Clindagel <sup>®</sup> (clindamycin 1% topical gel, generic)	75 mL bottle	150 mL	450 mL
Evoclin®	50 gram aerosol can	100 grams*	300 grams <sup><math>\Omega</math></sup>
(clindamycin 1% topical foam, generic)	100 gram aerosol can		

<sup>\*</sup> This is a quantity sufficient to cover 8% of the body surface area when applying twice daily for 30 days;  $^{\Omega}$  This is a quantity sufficient to cover 8% of the body surface area when applying twice daily for 90 days.

#### *Topical Antibiotics for Acne – Clindamycin DQM 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

Clindamycin phosphate 1% lotion (Cleocin T, generic) – twice daily application

 If the patient needs to treat acne on greater than 8% of their body surface area, approve the requested quantity, not to exceed 240 mL per 30 days at retail or 720 mL per 90 days at home delivery.

<u>Clindamycin phosphate 1% gel (generic only to formerly available Cleocin T gel) –</u> <u>twice daily application</u>

1. If the patient needs to treat acne on greater than 8% of their body surface area, approve the requested quantity, not to exceed 240 grams per 30 days at retail or 720 grams per 90 days at home delivery.

<u>Clindamycin phosphate 1% solution (generic only to formerly available Cleocin T solution) – twice daily application</u>

 If the patient needs to treat acne on greater than 8% of their body surface area, approve the requested quantity, not to exceed 240 mL per 30 days at retail or 720 mL per 90 days at home delivery.

<u>Clindamycin phosphate 1% gel (Clindagel, generic) – once daily application</u>

 If the patient needs to treat acne on greater than 8% of their body surface area, approve the requested quantity, not to exceed 300 mL per 30 days at retail or 900 mL per 90 days at home delivery.

Clindamycin phosphate 1% foam (Evoclin, generic)

1. If the patient needs to treat acne on greater than 8% of their body surface area, approve the requested quantity, not to exceed 200 grams per 30 days at retail or 600 grams per 90 days at home delivery.

# EXCLUSIONS

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

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

#### REFERENCES

- 1. Cleocin T 1% topical solution, gel, lotion [prescribing information]. New York, NY: Pfizer; January 2023.
- 2. Clindagel 1% gel [prescribing information]. Bridgewater, NJ: Bausch Health; January 2020.
- 3. Evoclin 1% foam [prescribing information]. Morgantown, WV: Mylan; April 2018.
- 4. Eichenfeld LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. *J Am Acad Dermatol*. 2014;71:116-132.
- 5. 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	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. Policy was updated to reflect the availability of brand Cleocin T 1% topical solution.	02/01/2023
Annual Revision	Brand Cleocin T 1% gel removed from the policy (product obsolete). Generic clindamycin 1% gel remains in the policy with no changes to quantity limits or override criteria.	02/08/2024
Annual Revision	No criteria changes.	02/07/2025

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