

# Quantity Limit; Post Limit Prior Authorization

## Clindamycin, Erythromycin Topical

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Clindagel	clindamycin	gel
Cleocin-T	clindamycin	gel, lotion, solution
Erygel	erythromycin	gel
erythromycin solution (brand unavailable)	erythromycin	solution

### Indications

#### FDA-approved Indications

##### Clindagel

Clindagel is indicated for topical application in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea, and pseudomembranous colitis, the physician should consider whether other agents are more appropriate.

##### Cleocin-T Gel, Lotion, Solution

Cleocin T Topical Solution, Cleocin T Topical Gel and Cleocin T Topical Lotion are indicated in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate

##### Erygel

Erygel Topical Gel is indicated for the topical treatment of acne vulgaris.

## Erythromycin Topical Solution

Erythromycin Topical Solution USP, 2% is indicated for the topical treatment of acne vulgaris.

## Initial Quantity Limit

### Initial Quantity Limit

If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Limits should accumulate across same chemical entity up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug	1 Month Limit	3 Month Limit
Clindagel (clindamycin gel)	75 mL / 25 days	225 mL / 75 days
Cleocin-T gel (clindamycin gel)	75 gm / 25 days	225 gm / 75 days
Cleocin-T lotion (clindamycin lotion)	60 mL / 25 days	180 mL / 75 days
Cleocin-T solution (clindamycin topical solution)	60 mL / 25 days	180 mL / 75 days
Erygel (erythromycin gel)	60 gm / 25 days	180 gm / 75 days
erythromycin topical solution	60 mL / 25 days	180 mL / 75 days

## Coverage Criteria

### Acne Vulgaris

Authorization may be granted when the requested drug is being prescribed for the topical treatment of acne vulgaris when the following criteria is met:

- The requested drug is NOT being used in a footbath

# Continuation of Therapy

## Acne Vulgaris

Authorization may be granted when the requested drug is being prescribed for the topical treatment of acne vulgaris when ALL of the following criteria are met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., reduction in number of lesions, patient satisfaction, etc.)
- The requested drug is NOT being used in a footbath

## Quantity Limits Apply

### Post Limit Quantity

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug	1 Month Limit	3 Month Limit
Clindagel (clindamycin gel)	150 mL / 25 days	450 mL / 75 days
Cleocin-T gel (clindamycin gel)	150 gm / 25 days	450 gm / 75 days
Cleocin-T lotion (clindamycin lotion)	120 mL / 25 days	360 mL / 75 days
Cleocin-T solution (clindamycin topical solution)	120 mL / 25 days	360 mL / 75 days
Erygel (erythromycin gel)	120 gm / 25 days	360 gm / 75 days
erythromycin topical solution	120 mL / 25 days	360 mL / 75 days

## Duration of Approval (DOA)

- 3697-HJ: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

## References

1. Clindagel [package insert]. Bridgewater, NJ: Bausch Health US, LLC. January 2020.
2. Cleocin-T Gel, Lotion, Solution [package insert]. New York, NY: Pharmacia & Upjohn Co; December 2019.

3. Erygel [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2018.
4. Erythromycin Topical Solution [package insert]. Allegan, MI: Padagis; May 2022.
5. Lexicomp Online, Lexi-Drugs Online, Hudson, OH: UpToDate, Inc.; 2024; Accessed July 17, 2024.
6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 07/17/2024).
7. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014; 71:116-32.
8. Elmetts CA, Korman NJ, Prater EF, et al. Joint AAD–NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021; 84:432-470.
9. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024; 90(5):1006.e1-1006.e30
10. Burn Triage and Treatment - Thermal Injuries. Available at: <https://chemm.hhs.gov/burns.htm>. Accessed July 17, 2024.