

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

PROTOPIC
(tacrolimus)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Protopic Ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable. Protopic ointment is not indicated for children younger than 2 years of age.

Compendial Uses

Psoriasis³ - on the face, genitals, or skin folds⁵

Vitiligo on the head or neck^{3,6,7}

Atopic Dermatitis for patients under 2 years of age (Protopic 0.03%)^{3,4}

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The request is for Protopic (tacrolimus) 0.03% ointment
OR
- The request is for Protopic (tacrolimus) 0.1% ointment **AND**
 - The patient is 16 years of age or older

AND

- The requested drug is being prescribed for psoriasis on the face, genitals, or skin folds OR vitiligo on the head or neck
OR
- The requested drug is being prescribed for moderate to severe atopic dermatitis (eczema) **AND**
 - The patient is less than 2 years of age
OR
 - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
OR
 - The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one first line therapy agent (e.g., medium or higher potency topical corticosteroid)

REFERENCES

1. Protopic [package insert]. Madison, NJ: Leo Pharma US, Inc.; February 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed February 17, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed February 17, 2022.
4. Eichenfield L, Tom W, et al. Guidelines of Care for the Management of Atopic Dermatitis. *J Am Acad Dermatol*. 2014;71:116-32.
5. Elmets 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 Feb;84(2):432-470.

6. Kubelis-López DE, Zapata-Salazar NA, et al. Updates and new medical treatments for vitiligo (Review). *Exp Ther Med.* 2021;22(2):797.
7. Eleftheriadou V, Atkar R, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021. *The British Journal of Dermatology.* 2021;186(1):18-29.