AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name: Tacrolimus Ointment		Page:	1 of 4
Effective Date: 5/1/2024		Last Review Date: 3/2024	
Applies to:	☐Illinois ☒New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia	☒Florida Kids ☐Michigan ☐Kentucky PRMD

Intent:
The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Tacrolimus Ointment under the patient's prescription drug benefit.

Description:
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
Psoriasis - on the face, genitals, or skin folds
Vitiligo on the head or neck
Atopic Dermatitis for patients under 2 years of age (Protopic 0.03%)

Applicable Drug List:
Preferred: Tacrolimus 0.1% Topical Ointment
Preferred: Tacrolimus 0.03% Topical Ointment

Policy/Guideline:
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

AND

- The request is NOT for continuation of therapy
  OR
- The request is for continuation of therapy
  AND
  - The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear, or almost clear outcome, patient satisfaction, etc.)

OR

- The requested drug is being prescribed for vitiligo on the head or neck
  AND
  - The request is NOT for continuation of therapy
    OR
  - The request is for continuation of therapy
    AND
    - The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation)

OR

- The requested drug is being prescribed for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis (eczema)
  AND
  - The request is NOT for continuation of therapy
    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)

OR

- The request is for continuation of therapy

  AND

  - The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]

Approval Duration and Quantity Restrictions:

Approval:

Short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis (eczema) in patients 2 years of age and older: Initial: 3 months; Renewal: 36 months

Short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis (eczema) in patients less than 2 years of age: Initial and Renewal: 3 months

Psoriasis on the face, genitals, or skin folds: Initial: 3 months; Renewal: 36 months

Vitiligo on the head or neck: Initial: 3 months; Renewal: 36 months

References:

1. Protopic [package insert]. Madison, NJ: Leo Pharma US, Inc.; February 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed February 21, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: February/21/2023).
4. Eichenfield L, Tom W, 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.

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.
8. Eichenfield LF, Tom WL, et. al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol 2014; 70:338-51.