Topical Immunomodulators (Elidel®, Protopic®, generics)

Policy # 00524
Original Effective Date: 01/01/2017
Current Effective Date: 06/20/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand/generic Protopic®‡ (tacrolimus ointment) and Elidel®‡ (pimecrolimus cream) for the treatment of atopic dermatitis or vitiligo to be **eligible for coverage** when the patient selection criteria are met.

Patient Selection Criteria
Coverage eligibility for brand/generic Protopic (tacrolimus ointment) or Elidel (pimecrolimus cream) will be considered when the following criteria are met for the requested indication and drug:

- For the treatment of atopic dermatitis:
  - Requested drug is brand/generic Protopic (tacrolimus ointment):
    - Patient has a diagnosis of moderate to severe atopic dermatitis, AND
    - Patient has tried and failed (e.g. intolerance or inadequate response) one prescription generic topical corticosteroid agent for the condition unless clinical evidence or patient history suggests the use of prescription generic topical corticosteroid agents will be/was ineffective or will/did cause an adverse reaction to the patient (e.g. atopic dermatitis lesions in sensitive areas such as the face or genital areas)
  - For Elidel (pimecrolimus cream) requests:
    - Patient has a diagnosis of mild to moderate atopic dermatitis, AND
    - Patient has tried and failed (e.g. intolerance or inadequate response) one prescription generic topical corticosteroid agent for the condition unless clinical evidence or patient history suggests the use of prescription generic topical corticosteroid agents will be/was ineffective or will/did cause an adverse reaction to the patient (e.g. atopic dermatitis lesions in sensitive areas such as the face or genital areas)
- For the treatment of vitiligo
  - Requested drug is generic tacrolimus ointment; AND
  - The patient has a diagnosis of vitiligo and ONE of the following:
    - Patient has tried and failed (e.g. intolerance or inadequate response) one prescription generic topical corticosteroid agent for a clinically sufficient duration unless clinical evidence or patient history suggests the use of prescription generic topical corticosteroid agents will be/was ineffective or will/did cause an adverse reaction to the patient; OR

- Disease is on the patient's face or other sensitive area (i.e. neck or skin folds)

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of brand/generic Protopic (tacrolimus ointment) or Elidel (pimecrolimus cream) for any indication other than atopic dermatitis or vitiligo (generic tacrolimus ointment only) to be **investigational.***

Based on review of available data, the Company considers the use of brand/generic Protopic (tacrolimus ointment) or Elidel (pimecrolimus cream) WITHOUT evidence that the patient has tried and failed one prescription generic topical corticosteroid agent for the condition to be **investigational.***

Background/Overview

Protopic is available as 0.03% and 0.1% strengths in ointment form. Protopic is also available as a generic under its active ingredient name, tacrolimus. Protopic and its generic are indicated for second line therapy for the short term and 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. Elidel is available in a 1% cream. The active ingredient in Elidel is pimecrolimus. Elidel carries a similar indication to Protopic, but is for mild to moderate atopic dermatitis. First line agents for the treatment of atopic dermatitis include topical corticosteroid agents (many of which are available in generic forms). Given that various topical corticosteroids exist in generic form, these offer a more economical, yet clinically effective alternative for treatment versus the topical immunomodulator agents.

Tacrolimus ointment is commonly used for the treatment of vitiligo on the face or areas at high risk for skin atrophy. Other treatment options for vitiligo include topical corticosteroids, phototherapy, and systemic corticosteroids. Topical corticosteroids may be more effective than topical tacrolimus ointment for non-facial vitiligo, but are associated with skin atrophy and other adverse events when used for a prolonged period.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Protopic was approved in 2000, and Elidel was approved in 2001. Both carry indications for the second line treatment of atopic dermatitis.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests a prescription generic topical corticosteroid agent will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above

mentioned caveats, there is no advantage of using brand/generic Protopic (tacrolimus ointment) or Elidel (pimecrolimus cream) over a prescription generic topical corticosteroid agent.

References

1. Protopic [package insert]. Astellas Pharma. Deerfield, Illinois. Updated November 2011.
2. Elidel [package insert]. Valeant Pharmaceuticals. Bridgewater, New Jersey. March 2014.
3. Vitiligo: Management and prognosis. UpToDate. Accessed May, 2018.

Policy History

Original Effective Date: 01/01/2017
Current Effective Date: 06/20/2018

08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. New policy.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Added vitiligo indication for generic tacrolimus ointment.

Next Scheduled Review Date: 06/2019

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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