Topical Immunomodulators (Elidel, Protopic, generics)

Policy # 00524
Original Effective Date: 01/01/2017
Current Effective Date: 01/01/2017

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 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 drug:

- For brand/generic Protopic (tacrolimus ointment) requests:
  - 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)

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 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 as 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.

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

Policy History

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08/04/2016 Medical Policy Committee review
08/17/2016 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 08/2017

*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 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:
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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.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
   A. In accordance with nationally accepted standards of medical practice;
   B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
   C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

† Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.