Atopic Dermatitis Agents –
Topical Immunosuppressive

WA.PHAR.42 Atopic Dermatitis Agents- Topical Immunosuppressive

Effective Date: May 1, 2020

Related medical policies:

- **WA.PHAR.43 Atopic Dermatitis Agents – Topical Phosphodiesterase 4 (PDE4) Inhibitors**

Note: New-to-market drugs are non-preferred and subject to this class/category prior authorization (PA) criteria. Non-preferred agents in this class/category, require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed.

Background:

Atopic dermatitis (AD) is a chronic, non-contagious, inflammatory disease of the skin resulting from a combination of genetic and environmental factors. Often referred to as "eczema," it is characterized by extremely dry, itchy skin on the insides of the elbows, behind the knees, and on the face, hands, and feet.

The American Academy of Dermatology guidelines for the care and management of atopic dermatitis recommend the use of topical corticosteroids in patients who have failed to respond to good skin care and regular use of emollients alone. The guidelines recommend using topical calcineurin inhibitors in the following situations: patients' refractory to topical corticosteroids, use in sensitive areas (e.g. face, axilla, anogenital region, and skin folds), patients with steroid induced-atrophy, and in patients who require long-term treatment.

Topical calcineurin inhibitors are immunosuppressive drugs that block cytokines (chemical messengers) that trigger the inflammatory response. Once absorbed into the skin, topical calcineurin inhibitors reduce symptoms of AD like redness and itchiness

Medical necessity

Drug	Medical Necessity
pimecrolimus (Elidel®) tacrolimus (Protopic®)	Topical immunosuppressives may be considered medically necessary when used as: • Second-line topical treatment of atopic dermatitis in patients 2 years of age and older **Note:** Non-preferred products require trial of a preferred product as indicated on the Apple Health Preferred Drug List. Requests for brand-name medications with a generic equivalent available must also meet the criteria described in the Brands with Generic Equivalents policy (Non-Clinical Policy No. 0001).

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Atopic Dermatitis pimecrolimus (Elidel®) tacrolimus (Protopic®)	Pimecrolimus and tacrolimus may be covered when ALL of the following are met: 1. Must be 2 years of age or older; **AND** 2. Have a diagnosis of atopic dermatitis with documentation of baseline evaluation of the disease, including severity of symptoms. 3. Trial of at least **TWO** topical corticosteroids (medium or higher potency) for daily treatment of minimum 14-days each in previous 6 months, unless contraindicated to all preferred topical corticosteroids: a. Contraindications include: i. Treatment of sensitive areas (face, anogenital, skin folds) not responding to low potency desonide or hydrocortisone; OR ii. History of steroid-induced atrophy; OR iii. Long-term uninterrupted topical steroid use; **AND** 4. Patient must **NOT** have **ANY** of the following: a. Immunocompromised status b. Severely impaired skin barrier (e.g., Netherton Syndrome) c. Risk/presence of malignancy (e.g., skin and lymphoma) 5. Age limits a. Pimecrolimus and tacrolimus 0.03%: greater than or equal to (≥) 2 years of age b. Tacrolimus 0.1%: Greater than or equal to (≥) 16 years of age **If ALL criteria are met, the request may be approved for 6 months**
	Criteria (Reauthorization)
	Pimecrolimus and tacrolimus may be reauthorized when ALL of the following are met: **1.** Clinical documentation of disease stability or improvement from baseline. **2. If ALL criteria are met, the request may be approved for 12 months**

Dosage and quantity limits

Drug Name	**Dose and Quantity** Limits **exception for prescriptions written by or in consultation with a specialist in dermatology*
pimecrolimus (Elidel®)	#1 (30g) tube per 28-days
tacrolimus (Protopic®) 0.03%	#1 (30g) tube per 28-days

tacrolimus (Protopic®) 0.1%	#1 (30g) tube per 28-days

References

1. DiPiro J, Talbert R, Yee G, Matzke G, Wells B, Posey L, et al. Pharmacotherapy: A Pathophysiologic Approach. 9th ed. New York, NY:McGraw-Hill; 2014.
2. U.S. Food and Drug Administration. "Dermatologic and Opthalmic Drugs Advisory Committee Meeting." FDA. 2016 Nov [cited 2016 Nov 9]; Available from: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DermatologicandOphthalm icDrugsAdvisoryCommittee/UCM436605.pdf Accessed December 2017.
3. Eichenfield L, Tom W, Berger T, et al. Guidelines of Care for the Management of Atopic Dermatitis. J Am Acad Dermatol. 2014;17(1):116-132.
4. Comparison of representative topical corticosteroid preparations. UpToDate. Available at: https://www.uptodate.com/home Accessed December 2017.

History

Date	Action and Summary of Changes
09/01/2022	Updated the not in the medical necessity section and removed reference to preferred and non-preferred products.
01/27/2020	Changed dose exception language to "prescriptions written by or in consultation with a specialist in dermatology." Updated date in footnote to January 27, 2020
01/13/2020	Effective date changed to May 1, 2020
01/07/2020	Changed dose limits to age limits and included exception statement for prescriptions written by dermatologists
10/11/2019	Clarification on initial authorization criteria 3.a.i. and reauthorization criteria 1.
09/24/2019	General formatting updates
08/21/2019	Updated documentation of baseline evaluation requirement
04/18/2018	New Policy