Washington State Health Care Authority

Atopic Dermatitis Agents – Topical Immunosuppressive

Medical policy no. 90.78.40 Effective Date: April 1, 2020

Related medical policies:

- **90.23.00 Atopic Dermatitis Agents – Topical Phosphodiesterase 4 (PDE4) Inhibitors**
- **90.27.30 Atopic Dermatitis Agents – Monoclonal Antibodies**

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:** Pimecrolimus is the preferred calcineurin inhibitor for the treatment of atopic dermatitis. Non-preferred products require trial of a preferred product

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Atopic Dermatitis Preferred agents: • pimecrolimus (Elidel®) Non-preferred agents: • 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. 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. Dose limits (exception for prescriptions written by dermatologist): 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
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
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