Washington State Health Care Authority

Topical Immunosuppressives - Calcineurin Inhibitors

Medical policy no. 90.78.40-2 Effective Date: TBD

Related medical policies:

Policy Name
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.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
pimecrolimus (Elidel)Click or tap here to enter text. tacrolimus	**Topical Immunosuppressive – Calcineurin Inhibitors** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. • Non-preferred brand name products on the Apple Health Preferred Drug List with an A-rated generic equivalent must also meet criteria in Non-Clinical Policy No. 0001 (NC-001). If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Atopic Dermatitis pimecrolimus (Elidel) tacrolimus	Tacrolimus or pimecrolimus (Elidel) may be approved when all of the following documented criteria are met: 1. The patient meets one of the following age criteria: a. For all pimecrolimus products, 2 years or older; **OR**

	b. For tacrolimus 0.03% products, 2 years or older; **OR** c. For tacrolimus 0.1% products, 16 years or older**; AND** 2. Diagnosis of atopic dermatitis; **AND** 3. Patient meets one of the following: a. Baseline body surface area (BSA) involvement is provided; **OR** b. Baseline disease severity scale scoring (e.g., Investigator's Global Assessment (IGA) score; Eczema Area and Severity Index (EASI), Patient Oriented Eczema Measure (POEM), etc.) is provided; **AND** 4. History of failure, contraindication, or intolerance to at least two different topical corticosteroids [minimum trial of 28 days each] a. Contraindications to topical corticosteroids include: i. Treatment of sensitive areas (face, anogenital, skin folds); **OR** ii. History of steroid-induced atrophy; **AND** 5. For non-preferred products, treatment with one Apple Health Preferred Drug List (PDL) medications has been ineffective, contraindicated, or not tolerated. If ALL criteria are met, the request will be authorized for **12 months.** **Criteria (Reauthorization)** Tacrolimus or pimecrolimus (Elidel) may be approved when all the following documented criteria are met: 1. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., reduction in body surface area involvement, achieved or maintained clear or minimal disease (equivalent to IGA sore of 0 or 1, experienced or maintained a decrease in EASI score)] from baseline. If ALL criteria are met, the request will be authorized for **12 months.**
Vitiligo Tacrolimus 0.1%	Tacrolimus 0.1% may be approved when all the following documented criteria are met: 1. The patient is 2 years of age or older**; AND** 2. Diagnosis of vitiligo that has been present for at least 3 months; **AND** 3. Baseline assessment of the disease, body surface area (BSA) involvement, and disease severity is provided; **AND** 4. History of failure, contraindication, or intolerance to at least two different medium-to-high potency topical corticosteroids (e.g. betamethasone, mometasone, clobetasol, fluocinonide) [minimum trial of 2 months each**]** a. Contraindications to topical corticosteroids include: i. Treatment of sensitive areas (face, anogenital, skin folds).

	ii. History of steroid-induced atrophy. If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Tacrolimus 0.1% may be approved when all the following documented criteria are met: 1. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., improvement in F-VASI and/or T-VASI score, or reduction in total BSA involvement] from baseline. If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Pimecrolimus (Elidel)	Atopic dermatitis	Apply to the affected skin twice daily	• 1% cream: 1 tube (up to 100 g) per 30 days
Tacrolimus	Atopic dermatitis	Apply to the affected skin twice daily	• 0.03% ointment: 1 tube (up to 100 g) per 30 days • 0.1% ointment: 1 tube (up to 100 g) per 30 days
	Vitiligo	Apply to the affected skin twice daily	• 0.03% ointment: 1 tube (up to 100 g) per 30 days • 0.1% ointment: 1 tube (up to 100 g) per 30 days

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

Vitiligo is a chronic autoimmune skin disorder which causes depigmentation on areas of skin. This depigmentation often has a psychological impact which includes depression, low self-esteem, and stigmatization.[5] "Topical corticosteroids are recommended for the treatment of vitiligo and carry risk with extended durations of use (e.g. skin atrophy). Topical calcineurin inhibitors are recommended for treatment, especially when areas of the face, anogenital, and skin folds are involved."[6]

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.
5. van Geel N, Speeckaert R, Taïeb A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the International Vitiligo Task Force Part 1: towards a new management algorithm. *J Eur Acad Dermatol Venereol*. 2023;37(11):2173-2184.
6. Seneschal J, Speeckaert R, Taïeb A, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: Position statement from the international Vitiligo Task Force-Part 2: Specific treatment recommendations. *J Eur Acad Dermatol Venereol*. 2023;37(11):2185-2195.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
TBD	**TBD**	90.78.40-2	
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

Washington State Health Care Authority

Calcineurin Inhibitors

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No

2. If request is non-preferred, has patient had treatment with one or more preferred topical immunosuppressive medications on the Apple Health Preferred Drug List (AHPDL) that was ineffective, contraindicated or not tolerated?
   ☐ Yes. List each medication and duration of trial:

   Medication Name: _____ Duration: _____
   Medication Name: _____ Duration: _____
   Medication Name: _____ Duration: _____

   ☐ No. Explain why a preferred product(s) have not been tried: _____

3. Indicate patient's body surface area (BSA) involvement:

   Baseline: _____ Date: _____
   Current: _____ Date: _____

4. Indicate patient's diagnosis:
   ☐ Atopic dermatitis (questions 5 – 8)
   ☐ Vitiligo (questions 9 – 13)
   ☐ Other, specify: _____

For diagnosis of atopic dermatitis:

5. Has documentation been submitted of patient's baseline disease severity scale scoring (e.g., Investigator's Global Assessment (IGA) score; Eczema Area and Severity Index (EASI), Patient Oriented Eczema Measure (POEM), etc.)?
   ☐ Yes ☐ No

6. Has patient had treatment with at least two different topical corticosteroids that has been ineffective, contraindicated or not tolerated (minimum trial of 28 days each)? ☐ Yes ☐ No

7. Indicate the following for patient. Check all that apply:
   ☐ Treatment is for sensitive areas (face, anogenital, skin folds)
   ☐ Documented history of steroid-induced atrophy

8. **For continuation of therapy:** Has documentation been submitted demonstrating disease stability or a positive clinical response [e.g., reduction in body surface area involvement, achieved or maintained clear or minimal disease from baseline (equivalent to IGA sore of 0 or 1, experienced or maintained a decrease in EASI score)] from baseline? ☐ Yes ☐ No

For diagnosis of vitiligo

9. Has patient had vitiligo for at least 3 months? ☐ Yes ☐ No

10. Has documentation been submitted of patient's baseline assessments of their disease and disease severity?
    ☐ Yes ☐ No

11. Has patient had treatment with at least two different medium-to-high potency topical corticosteroids (e.g. betamethasone, mometasone, clobetasol, fluocinonide) that has been ineffective, contraindicated or not tolerated (minimum trial of 2 months each)? ☐ Yes ☐ No

12. Indicate the following for patient. Check all that apply:
    ☐ Treatment is for sensitive areas (face, anogenital, skin folds)
    ☐ Documented history of steroid-induced atrophy

13. **For continuation of therapy:** Has documentation been submitted demonstrating disease stability or a positive clinical response [e.g., improvement in F-VASI and/or T-VASI score, or reduction in total BSA involvement] from baseline? ☐ Yes ☐ No

CHART NOTES AND BASELINE ASSESMENTS ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date