

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Anti-Inflammatory Medications**

**Medicaid and Health Choice
Effective Date: December 8, 2009
Amended Date:**

DRAFT

Therapeutic Class Code: Q5K, T0I

Therapeutic Class Description: Topical Anti-inflammatory Medications Calcineurin Inhibitors, Topical Anti-inflammatory Medications, Phosphodiesterase-4 (PDE4) Inhibitors

Medication
Elidel®, pimecrolimus cream
Protopic®, tacrolimus ointment
Eucrisa®
Opzelura™

Criteria:

Elidel®, pimecrolimus cream, Protopic® 0.03%, and tacrolimus 0.03%

- Beneficiary has tried and failed on at least one prescription topical corticosteroid and beneficiary is 2 years old or older.

OR

- Beneficiary has a documented adverse reaction or contraindication that precludes trial of one topical corticosteroid.

Eucrisa®:

- Beneficiary has tried and failed on at least one prescription topical corticosteroid and beneficiary is 3 months of age or older.

OR

- Beneficiary has a documented adverse reaction or contraindication that precludes trial of one topical corticosteroid.

Protopic® 0.1%, tacrolimus 0.1%:

- Beneficiary has tried and failed on at least one prescription topical corticosteroid and beneficiary is 18 years old or older.

OR

- Beneficiary has a documented adverse reaction or contraindication that precludes trial of one topical corticosteroid.

Procedures:

- May be approved for up to 1 year.

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Opzelura™:

Initial Approval:

- Recipient is ≥ 12 years old; **AND**
- Recipient has a diagnosis of mild to moderate atopic dermatitis; **AND**
- Recipient is NOT immunocompromised; **AND**
- Recipient has had a trial and failure, contraindication, or intolerance to ≥ 2 of the following classes:
 - Prescription topical corticosteroids
 - Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus)
 - Topical phosphodiesterase-4 inhibitor (e.g., crisaborole)

Procedures: Duration of Initial Approval: 8 weeks

Renewal Criteria:

- Recipient must continue to meet the above criteria; **AND**
- Recipient must have disease improvement and/or stabilization; **AND**
- Recipient has NOT experienced serious treatment-related adverse events (e.g., serious infections, lymphoma or other malignancies, non-melanoma skin cancer, major adverse cardiovascular events [MACE], thrombosis, thrombocytopenia, anemia, neutropenia; or lipid elevations).

Procedures: Duration of Renewal: 1 year

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References

1. Novartis Pharmaceuticals Corp., Elidel package insert. East Hanover, New Jersey 07936; May 2009.
2. Astellas Pharma US, INC. Protopic package insert. Deerfield, IL 60015-2548 ; June 2009.
3. Anacor Pharmaceuticals, INC., Eucrisa package insert. Palo Alto, California: December 2016.Updated March 2020.
4. Incyte Corporation., Opzelura™ prescribing information. Wilmington, DE. September 2021.

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Criteria Change Log

12/08/2009	Criteria effective date
06/13/2017	Add Eucrisa®
10/17/2017	Add Dupixent®
06/14/2019	Moved Dupixent® to the Monoclonal Antibody Criteria
06/14/2019	Added generic pimecrolimus, changed to try and fail one steroid instead of two, changed “patient” to “beneficiary”.
10/21/2020	Updated age for Eucrisa from 2 years to 3 months or older Changed to try and failure of one prescription topical corticosteroid
Xx/xx/xxxx	Added Opzelura