Tralokinumab

Adjudication Guideline

Rule Category:	Ref: No:	Version Control:	Effective Date:	Revision Date:
Pharmaceutical	2022-PH-012	Version No. V3.0	15/09/2022	22/10/2025

Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmaceutical Standards & Governance	N/A

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1. Abstract

1.1 For Members

Tralokinumab is a biologic drug approved by FDA for the treatment of moderate to severe atopic dermatitis. Moderate to severe atopic dermatitis is generally determined by your clinician by assessing how much body surface is affected and the severity of symptoms such as itch and rash that cannot be controlled by topical therapies.

Tralokinumab is available in injection form and administered through a subcutaneous route in the thighs or Abdomen.

1.2 For Medical Professionals

Tralokinumab an interleukin13 antagonist; monoclonal antibody is approved only in moderate to severe atopic dermatitis.

Dermatology physicians may prescribe this drug to member treatment in adult members whose disease is not adequately controlled with Topical therapies when those therapies are not advisable.

Tralokinumab Initial treatment is given for 16 weeks therapy per FDA approved dosage regiment, and treatment continuation is subject proven clinical efficacy by improvement in skin clarity, by using IGA and EASI-75 Scales.

2. Scope

The scope of this adjudication rule specifies the coverage details for medically necessary indications of Tralokinumab injection as per Daman's policy terms and conditions of each health insurance plan.

Tralokinumab is a fully human monoclonal antibody binding to the IL-13 cytokine and interleukin antagonist.

Tralokinumab is indicated for:

- the treatment of patients with moderate-to-severe atopic dermatitis.
- Treatment of adult patients who are candidate for systemic treatment or is not eligible for topical therapies or lack adequate response to topical treatment.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Medical Eligibility Criteria for Tralokinumab in Atopic Dermatitis

Coverage criteria

- Tralokinumab is covered only for FDA-approved indications.
- Indicated for the treatment of moderate-to-severe atopic dermatitis in adults and pediatric patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

- Must follow the FDA-approved dosing regimen and route of administration (subcutaneous injection in the thigh or abdomen).
- Treatment is covered for patients aged 12 years and above.
- Tralokinumab can be used with or without topical corticosteroids based on clinical judgment

Initial Eligibility Criteria

To initiate Tralokinumab therapy, the patient must meet **all** (A,B,C) of the following:

A. Confirmed Diagnosis of Moderate to Severe Atopic Dermatitis

Diagnosis must be supported by clinical evaluation and validated scoring tools, such as:
- DLQI ≥10 (Dermatology Life Quality Index)
- BSA >10% (Body Surface Area involvement)
- SCORAD ≥25 (Scoring Atopic Dermatitis)
- EASI ≥7 (Eczema Area and Severity Index)

B. Inadequate Response to Standard Therapy

Failure to achieve adequate control after ≥8 weeks of:
- Optimized topical corticosteroids
- Topical calcineurin inhibitors (TCIs)
- Phototherapy (e.g., NBUVB or UVA1), if feasible OR documented contraindication or intolerance to these therapies

C. Systemic Therapy Eligibility

Tralokinumab is recommended only for patients eligible for systemic therapy, defined by:
- Investigator's Global Assessment (IGA) score ≥3
- EASI score ≥16

Tralokinumab Refill criteria after 16 weeks of therapy for RESPONDERS:

Responders mean those who achieve.

- Investigator's Global Assessment (IGA) score of 0 (Clear) or 1 (Almost Clear) at Week 16 [Time Frame: At Week 16]

OR

- Patient Achieving at Least 75% Reduction in Eczema Area and Severity Index [EASI] at Week 16 [Time Frame: At Week 16]

3.2 Requirements for Coverage

- N/A

3.3 Non-Coverage

- Off-Label uses of Tralokinumab that are not FDA-approved indications or not included in the 'Coverage Criteria' section of this policy are considered experimental/investigational and are not covered benefits.
- Tralokinumab is not covered for visitor plans.
- Tralokinumab is not covered for any Off-Label approved indications.
- Tralokinumab is approved for patients aged 12 years and above; it is not indicated for pediatric patients under 12 years. Coverage should reflect this age criterion.
- Non-FDA-approved dosing regimens of Tralokinumab will not be covered.
- Tralokinumab is not covered during concomitant use of live vaccines. (Note: Inactivated vaccines can be administered per clinical judgment.)
- Patients with known primary immunodeficiency disorders are excluded from coverage.
- Patients with a history of anaphylaxis or severe hypersensitivity to any biological therapy, including Tralokinumab, are excluded.
- Administration of Tralokinumab by any route or method other than the FDA-approved subcutaneous injection (in the thigh or abdomen) will not be authorized/covered.
- Tralokinumab prescribed by clinicians outside the specialties of Dermatology and Allergy/Immunology will not be covered.

Eligible Clinician Specialties:

Eligible clinician specialty
Dermatologist
Dermatologist Allergist

3.4 Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Code	Code Description
MNEC-004	Service is not clinically indicated based on good clinical practice
CODE-010	Activity/diagnosis inconsistent with clinician specialty
MNEC-005	Service/supply may be appropriate, but too frequent
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender

Kindly use the below Pre-Requisite Form for Biological Therapy:

https://www.damanhealth.ae/Website/misc/Pre-requisite%20Form%20for%20Biologic%20Therapy.pdf

5. Appendices

5.1 References

- *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761180Orig1s000lbl.pdf*
- *https://www.ema.europa.eu/en/documents/product-information/adtralza-epar-product-information_en.pdf*
- *https://clinicaltrials.gov/ct2/show/NCT03131648*
- *https://www.clinicaltrials.gov/ct2/show/NCT03160885*
- *https://clinicaltrials.gov/ct2/show/NCT03363854*
- *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761180s001lbl.pdf*

5.2 Revision History

Date	Change(s)
12/8/2022	Release of V1.0
24/10/2024	AR review
22/10/2025	Guideline review/Updated medical eligibility criteria