STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRALOKINUMAB-LDRM	ADBRY	47741		GPI-10 (9027308045)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient has atopic dermatitis involving at least 10% of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   - The patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   - The patient had a trial of or contraindication to ONE preferred agent: Dupixent (dupilumab), Rinvoq (upadacitinib)
   - Adbry (tralokinumab-ldrm) will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or any JAK inhibitors (e.g., Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a trial of or contraindication to **TWO** of the following?
   - High or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate)
   - Topical calcineurin inhibitor (e.g., tacrolimus, Elidel [pimecrolimus])
   - Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole])
   - Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   - Phototherapy

   If yes, **enter two approvals by HICL or GPI-10 for a total of 6 months as follows:**
   - **<u>FIRST APPROVAL</u>: Approve with an end date of 30 days with a quantity limit of #6mL per 28 days.**
   - **<u>SECOND APPROVAL</u>: Approve for 5 months (enter a start date of 2 days before the end of the first approval) with a quantity limit of #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRALOKINUMAB-LDRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (a type of skin condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You have atopic dermatitis involving at least 10% of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc.)
E. You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
F. You had a trial of or contraindication (harmful for) to TWO of the following:
    1. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate)
    2. Topical calcineurin inhibitor (such as tacrolimus, Elidel [pimecrolimus])
    3. Topical PDE-4 inhibitor (Phosphodiesterase-4 Inhibitors such as Eucrisa [crisaborole])
    4. Topical JAK inhibitor (Janus kinase inhibitor such as Opzelura [ruxolitinib])
    5. Phototherapy (light therapy)
G. You had a trial of or contraindication (harmful for) to ONE preferred medication: Dupixent (dupilumab), Rinvoq (upadacitinib)
H. You will NOT use Adbry (tralokinumab-ldrm) concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or any JAK inhibitors (Janus kinase inhibitor such as Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRALOKINUMAB-LDRM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy
   - The patient had a trial of or contraindication to ONE preferred agent: Dupixent (dupilumab), Rinvoq (upadacitinib)
   - Adbry (tralokinumab-ldrm) will NOT be used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or any JAK inhibitors (e.g., Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe atopic dermatitis (a type of skin condition)
   B. You have shown improvement while on therapy
   C. You had a trial of or contraindication (harmful for) to ONE preferred medication: Dupixent (dupilumab), Rinvoq (upadacitinib)
   D. You will NOT use Adbry (tralokinumab-ldrm) concurrently (at the same time) with other systemic biologics (such as Dupixent [dupilumab]) or any JAK inhibitors (Janus kinase inhibitor such as Cibinqo [abrocitinib], topical Opzelura [ruxolitinib], Rinvoq [upadacitinib]) for the treatment of atopic dermatitis

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRALOKINUMAB-LDRM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adbry.

REFERENCES

- Adbry [Prescribing Information]. Ballerup, Denmark: LEO Pharma A/X; March 2023 .

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 01/22
Client Approval: 05/23
P&T Approval: 04/23