

09-J4000-20

Original Effective Date: 04/01/22

Reviewed: 11/12/25

Revised: 01/01/26

Subject: Tralokinumab-Idrm (Adbry[®]) Injection

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|--|------------------------------------|--------------------------------|-------------------------------|--|-----------------------------|
| Dosage/ Administration | Position Statement | Billing/Coding | Reimbursement | Program Exceptions | Definitions |
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DESCRIPTION:

Tralokinumab-Idrm (Adbry) is an interleukin-13 (IL-13) antagonist that was approved by the U.S. Food and Drug Administration (FDA) in December 2021 for “the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable”. Tralokinumab is the first IL-13 specific antagonist to be approved by the FDA. Dupilumab (Dupixent), approved for the treatment of atopic dermatitis in March 2017, inhibits both IL-4 and IL-13 by binding to the IL-4R alpha subunit shared by IL-4 and IL-13 receptors. In December 2023, the FDA-approved indication for atopic dermatitis was expanded to include adolescent patients aged 12 years and older. Tralokinumab is a human IgG4 monoclonal antibody that specifically binds to IL-13 and inhibits its interaction with the IL-13 receptor $\alpha 1$ and $\alpha 2$ subunits. IL-13 is a naturally occurring cytokine of the Type 2 immune response. Tralokinumab inhibits IL-13-induced responses including the release of proinflammatory cytokines, chemokines and IgE.

Atopic Dermatitis

Atopic dermatitis (AD), also known as atopic eczema, is a chronic, pruritic inflammatory dermatosis affecting up to 25% of children and approximately 7% of adults. AD follows a relapsing course and is associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and/or asthma. Onset is most common between 3 and 6 months of age, with approximately 60% of patients developing the eruption in the first year of life and 90% by age 5. While the majority of affected individuals have resolution of disease by adulthood, 10 to 30% do not, and a smaller percentage first develop symptoms as adults. AD has a complex pathogenesis involving genetic, immunologic, and environmental factors, which lead to a dysfunctional skin barrier and dysregulation of the immune system. Clinical findings include erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and lichenification. These clinical findings vary by patient age and chronicity of lesions. Pruritus is a hallmark of the condition that is responsible for much of the disease burden borne by

patients and their families. Typical patterns include facial, neck and extensor involvement in infants and children, flexure involvement in any age group, with sparing of groin and axillary regions.

Goals of treatment are to reduce symptoms (pruritus and dermatitis), prevent exacerbations, and minimize therapeutics risks. Despite its relapsing and remitting nature, the majority of patients with AD can achieve clinical improvement and disease control with topical emollient/moisturizer use and conventional topical therapies (including corticosteroids and calcineurin inhibitors). Moisturizers reduce signs, symptoms, and inflammation in AD, and can improve severity while also increasing time between flares. Moisturizers are considered generally safe and are strongly recommended to be used as part of a treatment regimen for AD, either as monotherapy or as concurrent use with pharmacologic treatments.

Topical therapies remain the mainstay of treatment due to their proven track record and generally favorable safety profile. They can be utilized individually or in combination with other topical, physical, and/or systemic treatments; as different classes of treatment have different mechanisms of action, combining therapies allows for the targeting of AD via multiple disease pathways. The American Academy of Dermatology (AAD) strongly recommends the following topical agents:

- Topical corticosteroids (TCS)
- Calcineurin inhibitors (TCIs) (e.g., tacrolimus, pimecrolimus)
- Topical PDE-4 inhibitors (e.g., crisaborole) [mild to moderate AD]
- Topical JAK inhibitors (e.g., ruxolitinib) [mild to moderate AD]

TCS are the most commonly utilized FDA-approved therapies in AD and are commonly used as first-line treatment for mild-to severe dermatitis in all skin regions. TCS target a variety of immune cells and suppress the release of proinflammatory cytokines. High to very high (super) potency TCS can be used to control flares and treat severe disease, while medium potency TCS are utilized for longer courses and as maintenance therapy. Lower potency TCS may be used, and it is important to consider the anatomical site (i.e., using lower potency agents on the face, neck, genitals, and body folds) and severity of the disease when choosing a steroid potency. Clinical trials assessing efficacy generally had a duration of 2 to 6 weeks, and response to TCS therapy should be evaluated by week 4 in clinical practice. Most studies of TCS in AD management involve twice daily application, but some studies (particularly for potent TCS) suggest once daily use may be sufficient. Traditionally, TCS were stopped once AD signs and symptoms of an AD flare were controlled. Maintenance in between AD flares with once to twice weekly use of TCS is another approach.

TCIs are a safe anti-inflammatory option for mild-to-severe AD, particularly when there is concern for adverse events secondary to corticosteroid use. Both tacrolimus and pimecrolimus have been shown to be effective in treating AD, but pimecrolimus may be more appropriate for patients who have milder disease or are sensitive to local reactions. Prescribing information for pimecrolimus cream and tacrolimus ointment indicate evaluation after 6 weeks if symptoms of AD do not improve for adults and pediatrics.

When AD is more severe or refractory to topical treatment, advanced treatment with phototherapy or systemic medications can be considered. Phototherapy is conditionally recommended by the AAD as a treatment for AD based on low certainty evidence. The AAD strongly recommends the following systemic therapies:

- Monoclonal antibodies (biologics) (e.g., dupilumab, tralokinumab)
- JAK inhibitors (e.g., upadacitinib, abrocitinib, baricitinib)

In a change from the 2014 AAD AD guidelines the use of systemic antimetabolites such as methotrexate, immunosuppressants such as systemic corticosteroids, mycophenolate mofetil, azathioprine, and cyclosporine are now conditionally recommended for AD only in a small number of select patients due to low or very low certainty of evidence and need for monitoring. The most favored first-line systemic is dupilumab.

There is no clear consensus on how to operationalize a definition of the FDA indication for treatment of patients with "moderate to severe" AD. The severity of AD can vary substantially over time and, from a patient's perspective, can include a complex combination of intensity of itch, location, body surface area (BSA) involvement, and degree of skin impairment. Given the variability of patient phenotype and lack of familiarity among clinicians with scoring systems used in clinical trials, it is advisable to create a broad clinically relevant definition inclusive of multiple specific measures of disease intensity for example:

- One of the following:
 - Affected BSA greater than or equal to 10%
 - Investigator Global Assessment (IGA) greater than or equal to 3
 - Eczema Area and Severity Index (EASI) greater than or equal to 16

OR

- One of the following:
 - Affected BSA greater than or equal to 10%
 - Involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds)
 - Severe itch that has been unresponsive to topical therapies

Efficacy

The efficacy of Adbry was assessed in three randomized, double-blind, placebo-controlled trials [ECZTRA 1 (NCT03131648), ECZTRA 2 (NCT03160885), and ECZTRA 3 (NCT03363854)]. Efficacy was assessed in a total of 1934 subjects 18 years of age and older with moderate-to-severe atopic dermatitis (AD) not adequately controlled by topical medication(s). Disease severity was defined by an Investigator's Global Assessment (IGA) score greater than or equal to 3 in the overall assessment of AD lesions on a severity scale of 0 to 4, an Eczema Area and Severity Index (EASI) score greater than or equal to 16 on a scale of 0 to 72, and a minimum body surface area (BSA) involvement of greater than or equal to 10%. At baseline, 58% of subjects were male, 69% of subjects were white, 50% of subjects had a baseline IGA score of 3 (moderate AD), and 50% of subjects had a baseline IGA score of 4 (severe AD). The baseline mean EASI score was 32 and the baseline weekly averaged Worst Daily Pruritus Numeric Rating Scale (NRS) was 8 on a scale of 0-10.

In all three trials, subjects received subcutaneous injections of Adbry 600 mg or placebo on Day 0, followed by 300 mg every other week or placebo for 16 weeks. Responders were defined as achieving an

IGA 0 or 1 (“clear” or “almost clear”) or EASI-75 (improvement of at least 75% in EASI score from baseline) at week 16.

To evaluate maintenance of response in the monotherapy trials (ECZTRA 1 and ECZTRA 2), subjects responding to initial treatment with Adbry 300 mg every other week were re-randomized to Adbry 300 mg every other week, Adbry 300 mg every 4 weeks or placebo every other week for another 36 weeks following first dose administration. Subjects randomized to placebo in the initial treatment period who achieved a clinical response at week 16 continued to receive placebo every other week for another 36 weeks. Non-responders at week 16, and subjects who lost clinical response during the maintenance period were placed on open-label treatment with Adbry 300 mg every other week and optional use of TCS.

The ECZTRA 3 trial studied the use of Adbry in combination with either a topical corticosteroid or topical calcineurin inhibitor. Subjects received either Adbry 300 mg every other week with TCS or placebo with TCS and as needed topical calcineurin inhibitors (TCI) until week 16. Subjects in the Adbry 300 mg with TCS group who achieved clinical response at week 16 were re-randomized to Adbry 300 mg every other week with TCS or Adbry every 4 weeks with TCS for another 16 weeks following first dose administration. Subjects in the placebo with TCS group who achieved clinical response at week 16 continued on placebo with TCS for another 16 weeks. Subjects who did not achieve clinical response at week 16 received Adbry 300 mg every other week for another 16 weeks. A mid-potency TCS (i.e., mometasone furoate 0.1% cream) was dispensed at each dosing visit. Subjects were instructed to apply a thin film of the dispensed TCS as needed once daily to active lesions from week 0 to week 32 and were to discontinue treatment with TCS when control was achieved. An additional, lower potency TCS or TCI could be used at the investigator’s discretion on areas of the body where use of the supplied TCS was not advisable, such as areas of thin skin.

All three trials assessed the primary endpoints of the proportion of subjects with an IGA 0 or 1 at week 16 and the proportion of subjects with EASI-75 at week 16. Secondary endpoints included the reduction of Worst Daily Pruritus NRS (weekly average) of at least 4 points on the 11-point itch NRS from baseline to week 16.

| | ECZTRA 1 | | ECZTRA 2 | | ECZTRA 3 | |
|---|-------------------------------|---------|-------------------------------|---------|-------------------------------------|---------------|
| | Adbry 300 mg every other week | Placebo | Adbry 300 mg every other week | Placebo | Adbry 300 mg every other week + TCS | Placebo + TCS |
| Number of subjects randomized and dosed (FAS)^a | 601 | 197 | 577 | 193 | 243 | 123 |
| IGA 0 or 1^{b,c} <i>Difference from Placebo (95% CI)</i> | 16% 9% (4%,13%) | 7% | 21% 12% (7%,17%) | 9% | 38% 9% (1%,21%) | 27% |
| EASI-75^c <i>Difference from Placebo (95% CI)</i> | 25% 9% (6%,18%) | 13% | 33% 9% (17%,28%) | 10% | 56% 9% (9%,30%) | 37% |
| Number of subjects with baseline Worst Daily Pruritus NRS (weekly average) score ≥ 4 | 594 | 194 | 563 | 192 | 240 | 123 |

| | | | | | | |
|--|---------------------|-----|----------------------|----|---------------------|-----|
| Worst Daily Pruritus NRS (≥ 4 point reduction)^c Difference from Placebo (95% CI) | 20% 10% (4%,15%) | 10% | 25% 16% (11%,21%) | 9% | 46% 11% (1%,22%) | 35% |
|--|---------------------|-----|----------------------|----|---------------------|-----|

- a. Full Analysis Set (FAS) includes all subjects randomized and dosed
- b. Responders was defined as a subject with an IGA 0 or 1 ("clear" or "almost clear")
- c. Subjects who received rescue treatment or with missing data were considered as non-responders

Note: Difference and 95% CI are based on the CMH test stratified by region and baseline IGA score

A higher proportion of subjects in the Adbry 300 mg every other week arm achieved EASI-90 compared to placebo in the three pivotal trials. Examination of age, gender, race, body weight, and previous treatment, including immunosuppressants, did not identify differences in response to Adbry 300 mg every other week among these subgroups.

In ECZTRA 1, 179 Adbry 300 mg every other week responders (IGA 0/1 or EASI-75) were re-randomized (and dosed) at week 16 to Adbry 300 mg every other week (68 subjects), Adbry 300 mg every 4 weeks (76 subjects) or placebo (35 subjects). Among these subjects, 39 subjects in Adbry 300 mg every other week arm, 36 subjects in Adbry 300 mg every 4 weeks arm and 19 subjects in placebo arm were IGA 0/1 responders at week 16. Maintenance of IGA 0/1 response at week 52 was as follows: 20 subjects (51%) in the every other week arm, 14 subjects (39%) in the every 4 weeks arm and 9 subjects (47%) in the placebo arm. Among the re-randomized subjects, 47 subjects in Adbry 300 mg every other week arm, 57 subjects in Adbry 300 mg every 4 weeks arm and 30 subjects in placebo arm were EASI-75 responders at week 16. Maintenance of EASI-75 response at week 52 was as follows: 28 subjects (60%) in the every other week arm, 28 subjects (49%) in the every 4 weeks arm and 10 subjects (33%) in the placebo arm.

In ECZTRA 2, 218 Adbry 300 mg every other week responders (IGA 0/1 or EASI-75) were re-randomized (and dosed) at week 16 to Adbry 300 mg every other week (90 subjects), Adbry 300 mg every 4 weeks (84 subjects) or placebo (44 subjects). Among these subjects, 53 subjects in Adbry 300 mg every other week arm, 44 subjects in Adbry 300 mg every 4 weeks arm and 26 subjects in placebo arm were IGA 0/1 responders at week 16. Maintenance of IGA 0/1 response at week 52 was as follows: 32 subjects (60%) in the every other week arm, 22 subjects (50%) in the every 4 weeks arm and 6 subjects (23%) in the placebo arm. Among the re-randomized subjects, 76 subjects in Adbry 300 mg every other week arm, 69 subjects in Adbry 300 mg every 4 weeks arm and 40 subjects in placebo arm were EASI-75 responders at week 16. Maintenance of EASI-75 response at week 52 was as follows: 43 subjects (57%) in the every other week arm, 38 subjects (55%) in the every 4 weeks arm and 8 subjects (20%) in the placebo arm.

In ECZTRA 3, 131 Adbry 300 mg every other week + TCS responders (IGA 0/1 or EASI-75) were re-randomized (and dosed) at week 16 to Adbry 300 mg every other week + TCS (65 subjects) or Adbry 300 mg every 4 weeks + TCS (66 subjects). Among these subjects, 45 subjects in Adbry 300 mg every other week + TCS arm and 46 subjects in Adbry 300 mg every 4 weeks + TCS arm were IGA 0/1 responders at week 16. Maintenance of IGA 0/1 response at week 32 was as follows: 40 subjects (89%) in the every other week arm and 35 subjects (76%) every 4 weeks arm. Among the re-randomized subjects, 65 subjects in Adbry 300 mg every other week arm and 62 subjects in Adbry 300 mg every 4 weeks arm were EASI-75 responders at week 16. Maintenance of EASI-75 response at week 32 was as follows: 60 subjects (92%) in the every other week arm and 56 subjects (90%) in the every 4 weeks arm.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of tralokinumab-ldrm (Adbry) **meets the definition of medical necessity** when **ALL** of the following criteria are met (“1” to “6”):

1. **ONE** of the following (“a”, “b”, or “c”):
 - a. The member has been treated with tralokinumab (starting on samples is not approvable) within the past 90 days
 - b. The prescriber states the member has been treated with tralokinumab (starting on samples is not approvable) within the past 90 days, **AND** is at risk if therapy is changed
 - c. **BOTH** of the following (“i” and “ii”):
 - i. Tralokinumab will be used for the treatment of an indication listed in the Table, and **ALL** of the indication-specific criteria are met
 - ii. **EITHER** of the following if the member has an FDA-approved indication (“I” or “II”):
 - I. The member’s age is within FDA labeling for the requested indication for tralokinumab
 - II. The prescriber has provided information in support of using tralokinumab for the member’s age for the requested indication
2. If the member has diagnosis of atopic dermatitis, then **BOTH** of the following (“a” and “b”):
 - a. **BOTH** of the following (“i” and “ii”):
 - i. The member is currently treated with topical emollients and practicing good skin care
 - ii. The member will continue the use of topical emollients and good skin care practices in combination with tralokinumab
 - b. **ONE** of the following (“i”, “ii”, or “iii”):
 - i. The member is initiating therapy with tralokinumab
 - ii. The member has been treated with tralokinumab for less than 16 consecutive weeks
 - iii. The member has been treated with tralokinumab for at least 16 consecutive weeks, **AND** **ANY** of the following:
 - The member is an adult (18 years and older), weighs less than 100 kg, and **ONE** of the following:
 - The member has achieved clear or almost clear skin **AND** the patient’s dose will be reduced to 300 mg every 4 weeks
 - The member has **NOT** achieved clear or almost clear skin

- The prescriber has provided information in support of therapy using 300 mg every 2 weeks
 - The member is an adult (18 years and older) and weighs greater than or equal to 100 kg
 - The member is less than 18 years old

3. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist, allergist, immunologist), **OR** the prescriber has consulted with a specialist in the area of the member's diagnosis
4. The member does **NOT** have any FDA labeled contraindications to Adbry
5. The member will **NOT** be using tralokinumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsimypti (etrasimod) and Zeposia (ozanimod)]
6. **ONE** of the following ("a" or "b"):
 - a. The requested quantity (dose) does **NOT** exceed the following:
 - i. Adults (18 years and older):
 - Loading dose - 600 mg (four 150 mg injections) x 1 dose
 - Maintenance dose – 300 mg (two 150 mg injections) every 2 weeks starting 2 weeks after the loading dose
 - QL: 150 mg/mL pre-filled syringes - 4 syringes (4 mL)/28 days
 - ii. Pediatric patients (12 to 17 years old):
 - Loading dose - 300 mg (two 150 mg injections) x 1 dose
 - Maintenance dose – 150 mg (one 150 mg injection) every 2 weeks starting 2 weeks after the loading dose
 - QL: 150 mg/mL pre-filled syringes - 2 syringes (2 mL)/28 days
 - b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium 1 or 2a recommended use) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit.

Approval duration: 6 months (loading dose approved for 1 month, then maintenance dose approved for the remainder of the 6 months)

TABLE 1

| Indications and Specific Criteria | |
|--|--------------------------|
| Indication | Specific Criteria |
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|---|---|
| Moderate-to-severe atopic dermatitis (AD) | <p>When BOTH of the following are met ("1" and "2"):</p> <ol style="list-style-type: none"> 1. ONE of the following ("a", "b", "c", or "d"): <ol style="list-style-type: none"> 1. The member has at least 10% body surface area involvement OR 2. The member has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) OR 3. The member has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 OR 4. The member has an Investigator Global Assessment (IGA) score of greater than or equal to 3 <p>AND</p> 2. EITHER of the following ("a" or "b"): <ol style="list-style-type: none"> a. BOTH of the following ("i" and "ii"): <ol style="list-style-type: none"> i. ONE of the following: <ul style="list-style-type: none"> • The member has tried and had an inadequate response to ONE at least a medium-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy OR The member has an intolerance or hypersensitivity to ONE at least a medium-potency topical corticosteroid used in the treatment of AD OR • The member has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD <p>AND</p> ii. ONE of the following: <ul style="list-style-type: none"> • The member has tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy |
|---|---|

| | |
|-------------------|--|
| | <p>OR</p> <ul style="list-style-type: none"> • The member has an intolerance or hypersensitivity to ONE topical calcineurin inhibitor used in the treatment of AD <p>OR</p> <ul style="list-style-type: none"> • The member has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD <p>OR</p> <ul style="list-style-type: none"> b. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AD |
| Other indications | The member has another FDA-approved indication for tralokinumab OR an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium 1 or 2a recommended use for tralokinumab |

Continuation of tralokinumab-ldrm (Adbry) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "7"):

1. An authorization or reauthorization for tralokinumab has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. The member has had clinical benefit with tralokinumab
3. If the member has diagnosis of atopic dermatitis, **BOTH** of the following ("a" and "b"):
 - a. If the member has a diagnosis of moderate-to-severe atopic dermatitis, the member will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with tralokinumab
 - b. **ONE** of the following ("i", "ii", or "iii"):
 - i. The member is initiating therapy with tralokinumab
 - ii. The member has been treated with tralokinumab for less than 16 consecutive weeks
 - iii. The member has been treated with tralokinumab for at least 16 consecutive weeks, **AND ANY** of the following:
 - The member is an adult (18 years and older), weighs less than 100 kg, and **ONE** of the following:
 - The member has achieved clear or almost clear skin, **AND** the patient's dose will be reduced to 300 mg every 4 weeks
 - The member has **NOT** achieved clear or almost clear skin
 - There is support for therapy using 300 mg every 2 weeks
 - The member is an adult (18 years and older) and weighs greater than or equal to 100 kg
 - The member is less than 18 years old

4. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist, allergist, immunologist), **OR** the prescriber has consulted with a specialist in the area of the member's diagnosis
5. The member will **NOT** be using tralokinumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinco (abrocitinib), Leqselvi (deuruxolitinib), Litfuro (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. The member does **NOT** have any FDA-labeled contraindications to Adbry
7. **ONE** of the following ("a" or "b"):
 - a. The requested quantity (dose) does **NOT** exceed the following:
 - Adults (18 years and older) - 300 mg (two 150 mg injections) every 2 weeks
 - QL: 150 mg/mL pre-filled syringes - 4 syringes/28 days
 - Pediatric patients (12 to 17 years old) - 150 mg (one 150 mg injection) every 2 weeks
 - QL: 150 mg/mL pre-filled syringes - 2 syringes (2 mL)/28 days
 - b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Tralokinumab is indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Tralokinumab can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas.
- The recommended subcutaneous injection dosage is:
 - Adults (18 years and older)
 - An initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week.

- After 16 weeks of treatment, for patients with body weight below 100 kg who achieve clear or almost clear skin, a dosage of 300 mg every 4 weeks may be considered.
- Pediatric patients (12 to 17 years old)
 - An initial dose of 300 mg (two 150 mg injections), followed by 150 mg (one 150 mg injection) administered every other week.

Dose Adjustments

- Hepatic Impairment - Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed.
- Renal Impairment - Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no dosage adjustments are needed.

Drug Availability

- Pack sizes containing 2 or 4 prefilled syringes (150 mg/mL) with needle guard

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Known hypersensitivity to tralokinumab or any of its excipients

Precautions/Warnings

- **Hypersensitivity** - Hypersensitivity reactions including anaphylaxis and angioedema, have been reported with use. If a serious hypersensitivity reaction occurs, discontinue immediately and initiate appropriate therapy.
- **Conjunctivitis and Keratitis** - Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received tralokinumab. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.
- **Parasitic (Helminth) Infections** - Patients with known helminth infections were excluded from participation in clinical studies. It is unknown if tralokinumab will influence the immune response against helminth infections by inhibiting IL-13 signaling. Treat patients with pre-existing helminth infections before initiating treatment with tralokinumab. If patients become infected while receiving tralokinumab and do not respond to antihelminth treatment, discontinue treatment with tralokinumab until the infection resolves.
- **Risk of Infection with Live Vaccines** - Tralokinumab may alter a patient's immunity and increase the risk of infection following administration of live vaccines. Prior to initiating therapy with tralokinumab, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with tralokinumab. Limited data are available regarding coadministration of tralokinumab with non-live vaccines.

- **Immunogenicity** - Across all trial periods, the Anti-Drug-Antibodies (ADA) incidence for subjects who received tralokinumab was 4.6%; 0.9% had persistent ADA and 1% had neutralizing antibodies. No clinically meaningful differences in the pharmacokinetics, safety, or efficacy of tralokinumab were observed in patients who tested positive for anti-tralokinumab antibody (including neutralizing antibodies).
- **Pregnancy** - There are limited data from the use of tralokinumab in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Refer to the product label for more information.
- **Lactation** - There are no data on the presence of tralokinumab in human milk, the effects on the breastfed infant, or the effects on milk production. Refer to the product label for more information.

BILLING/CODING INFORMATION:

HCPCS Coding

| | |
|--------|--------------------------------|
| L20.0 | Besnier's prurigo |
| L20.81 | Atopic neurodermatitis |
| L20.82 | Flexural eczema |
| L20.84 | Intrinsic (allergic) eczema |
| L20.89 | Other atopic dermatitis |
| L20.9 | Atopic dermatitis, unspecified |

ICD-10 Diagnosis Codes That Support Medical Necessity

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| J3590 | Unclassified biologics |
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REIMBURSEMENT INFORMATION:

Refer to section entitled [**POSITION STATEMENT**](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

Eczema Area Severity Index score (EASI) - assesses severity (severity score) and body surface area affected by erythema, induration/papulation/edema, excoriations, and lichenification (area score), which are graded systematically for each of 4 anatomical regions (head and neck, trunk, upper limbs, lower limbs) and assembled in a composite score, with a score range of 0 to 72.

- EASI 50 - a percentage improvement of EASI score from baseline that is $\geq 50\%$
- EASI 75 - a percentage improvement of EASI score from baseline that is $\geq 75\%$
- EASI 90 - a percentage improvement of EASI score from baseline that is $\geq 90\%$

Helper T cells (a.k.a., CD4+ T cells) – a type of lymphocyte or white blood cell (WBC) that matures in the thymus and play an important role in cell-mediated immunity. T helper cells assist other WBCs in immunologic processes by releasing T cell cytokines. Different types of T helper cells secrete different cytokines (e.g., type 2 release IL-4, IL-5, IL-9, IL-10 and IL-13)

Patient-Oriented Eczema Measure (POEM) – a validated questionnaire, examining seven items (scored 0 to 4 based on frequency of event), used in clinical settings to assess time spent with symptoms and the impact of symptoms on sleep, with a score range of 0 to 28.

Pruritus – itching

Scoring Atopic Dermatitis (SCORAD) - the extent and severity of AD over the body area and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) are assessed and scored by the investigator. Subjective assessment of itch and sleeplessness is scored by the patient. The SCORAD score is a combined score of body area affected, and investigator and patient symptom scoring, with a score range of 0 to 103.

RELATED GUIDELINES:

[Abrocitinib \(Cibiniq\), 09-J4000-27](#)

[Dupilumab \(Dupixent\), 09-J2000-80](#)

[Upadacitinib \(Rinvoq\), 09-J3000-51](#)

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at [Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy](#).

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/13/24.

GUIDELINE UPDATE INFORMATION:

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| 04/01/22 | New Medical Coverage Guideline. |
| 06/15/22 | Revision to the guideline consisting of updating the position statement to remove the prerequisite use of dupilumab (Dupixent). |
| 01/01/23 | Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination. |
| 04/15/23 | New drugs were added to the list of drugs that are not permitted for use in combination. |
| 07/01/23 | Revision to guideline consisting of updating the other section. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy. |
| 01/01/24 | Review and revision to guideline consisting of updating the description (atopic dermatitis info), position statement, other section, and references. Added additional |

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| | parameters for diagnosis of “moderate-to-severe” atopic dermatitis. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination. |
| 04/01/24 | Revision to guideline consisting of updating the description section, position statement, dosage/administration, and references. Updated with expanded FDA-approved age for the treatment of atopic dermatitis (AD) and removal of the step requirement of a systemic immunosuppressant for AD (based on new AD guidelines). |
| 07/01/24 | Revision to guideline consisting of updating the position statement and other section. Approval duration for new starts is 12 months. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy. |
| 01/01/25 | Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination. |
| 01/01/26 | Review and revision to guideline consisting of updating the description, position statement and references. |