

09-J5000-37

Original Effective Date: 03/15/26

Reviewed: 02/11/26

Revised: 00/00/00

Subject: Interleukin 13 (IL-13) Antagonists

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Tralokinumab-ldrm (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.

Lebrikizumab-lbkz (Ebglyss) is an IL-13 receptor antagonist approved by the US Food and Drug Administration (FDA) in September 2024 for the treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Lebrikizumab is the second IL-13 specific antagonist to be approved by the FDA; the first being tralokinumab (Adbry).

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 therapeutic 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 - Adbry

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	25%	13%	33%	10%	56%	37%

<i>Difference from Placebo (95% CI)</i>	9% (6%,18%)		9% (17%,28%)		9% (9%,30%)	
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 <i>Difference from Placebo (95% CI)</i>	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.

Efficacy - Ebglyss

Three multicenter, randomized, double-blind, placebo-controlled trials, ADvocate 1, ADvocate 2 and ADhere (NCT04146363, NCT04178967, NCT04250337) enrolled a total of 1,062 subjects 12 years of age and older with moderate-to-severe atopic dermatitis not adequately controlled by topical medication(s) and who were candidates for systemic therapy. A total of 148 subjects (14%) were 12 to less than 18 years who weighed at least 40 kg and 914 (86%) were adult subjects. 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 involvement of greater than or equal to 10%.

At baseline, 63% of subjects had a baseline IGA score of 3 (moderate AD) and 37% of subjects had a baseline IGA of 4 (severe AD). The baseline mean EASI was 29, and the baseline Pruritus Numeric Rating Scale (NRS) was 7 on a scale of 0-10. Of all subjects, 99% had received prior treatment for AD.

In all three trials, subjects in the Ebglyss group received subcutaneous injections of Ebglyss 500 mg at Week 0 and at Week 2, followed by 250 mg every other week (Q2W) through Week 16. To evaluate the maintenance and durability of response in the monotherapy trials (ADvocate 1 and ADvocate 2), subjects originally randomized to Ebglyss who achieved an IGA score of 0 or 1, or at least a 75% reduction in EASI from baseline [EASI-75] at Week 16 and did not require rescue therapy were re-randomized to an additional 36 weeks of either a maintenance dose of Ebglyss 250 mg Q2W (every 2 weeks), Ebglyss 250 mg Q4W (every 4 weeks), or placebo. Subjects who did not achieve IGA 0 or 1 or EASI-75 at Week 16 or subjects who required rescue therapy during the first 16 weeks were treated with open-label Ebglyss 250 mg Q2W. In the concomitant therapy trial (ADhere), subjects received Ebglyss + TCS or placebo + TCS. Topical calcineurin inhibitors (TCI) were permitted for sensitive areas only, such as the face, neck, intertriginous and genital areas.

All three trials assessed the primary endpoint, the proportion of subjects who achieved an IGA score of 0 (clear) or 1 (almost clear) and at least a 2-point improvement from baseline at Week 16. Other evaluated outcomes at Week 16 included the proportion of subjects with EASI-75 and EASI-90, and improvement in itch severity as defined by a reduction of at least 4 points on an 11-point Pruritus NRS. ADvocate 1 and ADvocate 2 also evaluated the maintenance and durability of response through Week 52. The results of the Ebglyss monotherapy trials (ADvocate 1 and ADvocate 2) are presented below:

	ADvocate 1			ADvocate 2		
	Ebglyss 250 mg Q2W	Placebo	Difference from Placebo (95% CI)	Ebglyss 250 mg Q2W	Placebo	Difference from Placebo (95% CI)
Number of subjects	283	141	--	281	146	--

IGA 0 or 1 and a reduction of at least 2 points	43%	13%	30% (22%, 38%)	33%	11%	22% (14%, 30%)
EASI-75	59%	16%	42% (33%, 51%)	52%	18%	33% (24%, 42%)
EASI-90	38%	9%	29% (21%, 36%)	31%	10%	21% (13%, 28%)
Number of subjects with baseline Pruritus NRS score greater than or equal to 4	263	130	--	253	134	--
Pruritus NRS greater than or equal to 4 point improvement	46%	13%	33% (25%, 41%)	40%	12%	28% (20%, 37%)

The results in the concomitant therapy trial (ADhere) at Week 16, where subjects received Ebglyss + TCS or placebo + TCS were consistent with the results in the monotherapy trials (ADvocate 1 and ADvocate 2).

Ebglyss-treated subjects achieving IGA 0 or 1 or EASI-75, and who did not receive rescue therapy at Week 16 were re-randomized to 36 weeks of maintenance treatment with Ebglyss 250 mg Q2W, Ebglyss 250 mg Q4W, or placebo in ADvocate 1 and ADvocate 2. The results are presented below:

	ADvocate 1			ADvocate 2		
	Ebglyss 250 mg Q2W	Ebglyss 250 mg Q4W	Placebo	Ebglyss 250 mg Q2W	Ebglyss 250 mg Q4W	Placebo
Number of subjects who were IGA of 0 or 1 responders at Week 16	45	45	22	32	32	16
IGA or 0 or 1 at Week 52	76%	74%	47%	65%	81%	50%
Number of subjects who were EASI-75 Responders at Week 16	61	62	30	51	53	27
EASI-75 at Week 52	79%	79%	61%	77%	85%	72%

Combining the results of ADvocate 1 and ADvocate 2, the proportion of patients who maintained an IGA of 0 or 1 with a greater than or equal to 2-point improvement at week 52 was 71.2%, 76.9% and 47.9% in those assigned to the lebrikizumab Q2W, lebrikizumab Q4W and lebrikizumab withdrawal treatment arms, respectively. At week 52, patients assigned to the lebrikizumab Q2W, lebrikizumab Q4W and lebrikizumab withdrawal treatment arms exhibited durable EASI 75 response rates of 78.4%, 81.7% and 66.4%, respectively.

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 lebrikizumab-lbkz (Ebglyss) or 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 the requested agent (starting on samples is not approvable) within the past 90 days
 - b. The prescriber states the member has been treated with the requested agent (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. The requested agent 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 the requested agent
 - II. The prescriber has provided information in support of using the requested agent 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 the requested agent
 - b. **ONE** of the following depending on the agent requested:
 - I. If Adbry – **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
 - II. If Ebglyss - the member weighs 40 kg (88 lbs) or greater
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 the requested agent
5. The member will **NOT** be using the agent requested in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Anzupgo (delgocitinib 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 [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ONE** of the following ("a", "b", or "c"):
 - a. The requested quantity (dose) does **NOT** exceed the following based on the agent requested:
 - I. Adbry
 - 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
 - II. Ebglyss
 - Loading dose - 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg (one injection) every 2 weeks until Week 16 [ten total 250 mg injections - four 250 mg injections for the first 28 days, followed by two 250 mg injections per 28 days for the next three 28-day periods]
 - Maintenance dose - 250 mg every 4 weeks [starting on Week 16]
 - QL: 250 mg/2 mL pre-filled syringes - 1 syringe/28 days
 - QL: 250 mg/2 mL pen - 1 pen/28 days
 - b. For a diagnosis of atopic dermatitis and for Ebglyss **ONLY – BOTH** of the following ("i" and "ii"):
 - i. There is support for therapy for the dose exceeding the quantity limit (e.g., the patient has not achieved adequate clinical response on 250 mg every 2 weeks during the initial 16 week induction dosing) (medical records required)
 - ii. The requested quantity (dose) does NOT exceed 250 mg every 2 weeks
 - c. 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:

- Adbry - 6 months (loading dose approved for 1 month, then maintenance dose approved for the remainder of the 6 months)
- Ebglyss - 6 months (loading doses approved for 16 weeks, then maintenance dose approved for the remainder of the 6 months)

TABLE 1

Indications and Specific Criteria	
Indication	Specific Criteria
Moderate-to-severe atopic dermatitis (AD)	<p>When BOTH of the following are met (“1” and “2”):</p> <ol style="list-style-type: none"> ONE of the following (“a”, “b”, “c”, or “d”): <ol style="list-style-type: none"> The member has at least 10% body surface area involvement <p>OR</p> <ol style="list-style-type: none"> 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) <p>OR</p> <ol style="list-style-type: none"> The member has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 <p>OR</p> <ol style="list-style-type: none"> The member has an Investigator Global Assessment (IGA) score of greater than or equal to 3 <p>AND</p> EITHER of the following (“a” or “b”): <ol style="list-style-type: none"> BOTH of the following (“i” and “ii”): <ol style="list-style-type: none"> 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 <p>OR</p> The member has an intolerance or hypersensitivity to ONE at least a medium-potency topical corticosteroid used in the treatment of AD

	<p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • The member has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD <p style="text-align: center;">AND</p> <p>ii. ONE of the following:</p> <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 style="text-align: center;">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 style="text-align: center;">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 style="text-align: center;">OR</p> <p>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</p>
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

Continuation of lebrikizumab-lbkz (Ebglyss) or tralokinumab-ldrm (Adbry) **meets the definition of medical necessity** when **ALL** of the following criteria are met (“1” to “8”):

1. An authorization or reauthorization for the requested agent 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 the requested agent
3. 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 the requested agent
4. For a diagnosis of atopic dermatitis and for Adbry **ONLY** - **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
5. 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
6. The member will **NOT** be using the requested agent in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Anzupgo (delgocitinib), Cibinco (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (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)]
7. The member does **NOT** have any FDA-labeled contraindications to the requested agent
8. **ONE** of the following ("a", "b", or "c"):
 - a. The requested quantity (dose) does **NOT** exceed the following based on the agent requested:
 - i. Adbry
 - 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
 - ii. Ebglyss
 - Loading dose - 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg (one injection) every 2 weeks until Week 16 [ten total 250 mg injections - four 250 mg injections for the first 28 days, followed by two 250 mg injections per 28 days for the next three 28-day periods]
 - Maintenance dose - 250 mg every 4 weeks [starting on Week 16]
 - QL: 250 mg/2 mL pre-filled syringes - 1 syringe/28 days
 - QL: 250 mg/2 mL pen - 1 pen/28 days
 - b. For a diagnosis of atopic dermatitis and for Ebglyss **ONLY – BOTH** of the following ("i" and "ii"):

- i. There is support for therapy for the dose exceeding the quantity limit (e.g., the patient has not achieved adequate clinical response on 250 mg every 2 weeks during the initial 16 week induction dosing) (medical records required)
- ii. The requested quantity (dose) does NOT exceed 250 mg every 2 weeks
- c. 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

Adbry

- 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.

Ebglyss

- Treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Lebrikizumab can be used with or without topical corticosteroids

- The recommended dosage is 500 mg (two 250 mg injections) at Week 0 and Week 2, followed by 250 mg (one injection) every 2 weeks until Week 16 or later, when adequate clinical response is achieved. The maintenance dose is 250 mg every 4 weeks.

Dose Adjustments

Adbry

- 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.

Ebglyss

- 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

Adbry

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

Ebglyss

- 250 mg/2 mL in a single-dose prefilled pen
- 250 mg/2 mL in a single-dose prefilled syringe with needle shield

PRECAUTIONS:

Boxed Warning

Adbry

- None

Ebglyss

- None

Contraindications

Adbry

- Known hypersensitivity to tralokinumab or any of its excipients

Ebglyss

- Prior serious hypersensitivity to lebrikizumab-lbkz or any excipients in Ebglyss

Precautions/Warnings

Adbry

- **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.

Ebglyss

- **Hypersensitivity** - Hypersensitivity reactions including angioedema and urticaria, have occurred after administration of Ebglyss. Discontinue Ebglyss in the event of a serious hypersensitivity reaction.
- **Conjunctivitis and Keratitis** - Report new onset or worsening eye symptoms to a healthcare provider.
- **Parasitic (Helminth) Infections** - Treat patients with pre-existing helminth infections before initiating Ebglyss. If patients become infected while receiving Ebglyss and do not respond to antihelminth treatment, discontinue treatment with Ebglyss until the infection resolves.

- **Vaccinations** - Avoid use of live vaccines during treatment with Ebglyss.

BILLING/CODING INFORMATION:

HCPCS Coding

Adbry and Ebglyss

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

J3590	Unclassified biologics (for both Adbry and Ebglyss)
-------	---

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 \(Cibinqo\), 09-J4000-27](#)

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

[Nemolizumab \(Nemluvio\), 09-J4000-99](#)

[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](#).

REFERENCES:

1. Adbry (tralokinumab-ldrm injection) [package insert]. Madison, NJ: LEO Pharma Inc., June 2024.
2. Anderson K, Putterman E, Rogers RS, et al. Treatment of severe pediatric atopic dermatitis with methotrexate: A retrospective review. *Pediatr Dermatol*. 2019 Feb 27. [Epub ahead of print]
3. Ashcroft DM, Dimmock P, Garside R, et al. Efficacy and tolerability of topical pimecrolimus and tacrolimus in the treatment of atopic dermatitis: meta-analysis of randomised controlled trials. *BMJ*. 2005;330(7490):516.
4. Bieber T. Atopic dermatitis. *Engl J Med*. 2008 Apr 3;358(14):1483-94.
5. Clinical Pharmacology powered by ClinicalKey [Internet]. Tampa, FL: Elsevier.; 2025. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed 10/29/25.
6. Cury Martins J, Martins C, Aoki V, et al. Topical tacrolimus for atopic dermatitis. *Cochrane Database Syst Rev*. 2015 Jul 1;(7):CD009864.
7. Davis DMR, Drucker AM, Alikhan A, et al. American Academy of Dermatology Guidelines: Awareness of comorbidities associated with atopic dermatitis in adults. *J Am Acad Dermatol*. 2022;86(6):1335-1336.e18.

8. Davis DMR, Frazer-Green L, Alikhan A, et al. Focused update: Guidelines of care for the management of atopic dermatitis in adults. *J Am Acad Dermatol*. 2025 Sep;93(3):745.e1-745.e7.
9. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol* 2024;90(2):e43-e56.
10. Drake LA, Dinehart SM, Farmer ER, et al: Guidelines of care for the use of topical glucocorticosteroids. *J Am Acad Dermatol* 1996; 35:615-619.
11. Ebglyss (lebrikizumab-lbkz injection, for subcutaneous use) [package insert]. Indianapolis, IN: Eli Lilly and Company: October 2025.
12. Eichenfield LF, Tom WL, Chamlin SL, et al. Guidelines of care for the management of atopic dermatitis. Section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol*. 2014 Feb;70(2):338-51.
13. European Task Force on Atopic Dermatitis (ETFAD) / European Academy of Dermatology and Venereology (EADV) Eczema Task Force Position Paper on Diagnosis and Treatment of Atopic Dermatitis in Adults and Children. *J Eur Acad Dermatol Venereol*. 2020;34(12):2717-2744.
14. Galli E, Neri I, Ricci G, et al. Consensus Conference on Clinical Management of pediatric Atopic Dermatitis. *Ital J Pediatr*. 2016 Mar 2; 42:26.
15. Gutermuth J, Pink AE, Worm M, et al. Tralokinumab plus topical corticosteroids in adults with severe atopic dermatitis and inadequate response to or intolerance of ciclosporin A: a placebo-controlled, randomized, phase III clinical trial (ECZTRA 7). *Br J Dermatol*. 2021 Oct 26. Epub ahead of print.
16. Institute For Clinical and Economic Review (ICER). JAK Inhibitors and Monoclonal Antibodies for the Treatment of Atopic Dermatitis: Effectiveness and Value. Final Evidence Report. August 2021. Updated February 2023.
17. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 10/29/24.
18. Mortz CG, Andersen KE, Dellgren C, et al. Atopic dermatitis from adolescence to adulthood in the TOACS cohort: prevalence, persistence and comorbidities. *Allergy*. 2015 Jul;70(7):836-45.
19. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2024 [2024 Oct 29]. Available from: <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/>.
20. Ring J, Alomar A, Bieber T, et al; European Dermatology Forum (EDF), European Academy of Dermatology and Venereology (EADV), European Federation of Allergy (EFA), European Task Force on Atopic Dermatitis (ETFAD), European Society of Pediatric Dermatology (ESPD), Global Allergy and Asthma European Network (GA2LEN). Guidelines for treatment of atopic eczema (atopic dermatitis) part I. *J Eur Acad Dermatol Venereol*. 2012 Aug;26(8):1045-60.
21. Roekevisch E, Spuls PI, Kuester D, et al. Efficacy and safety of systemic treatments for moderate-to-severe atopic dermatitis: a systematic review. *The Journal of allergy and clinical immunology*. 2014;133(2):429-438.
22. Schmitt J, von Kobyletzki L, Svensson A, et al. Efficacy and tolerability of proactive treatment with topical corticosteroids and calcineurin inhibitors for atopic eczema: systematic review and meta-analysis of randomized controlled trials. *Br J Dermatol*. 2011;164(2):415.
23. Shaw TE, Currie GP, Koudelka CW, et al. Eczema prevalence in the United States: data from the 2003 National Survey of Children's Health. *J Invest Dermatol*. 2011;131(1):67.
24. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.

25. Sidbury R, Tom WL, Bergman JN, et al. Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches. *J Am Acad Dermatol*. 2014 Dec;71(6):1218-33.
26. Siegfried EC, Jaworski JC, Kaiser JD, et al. Systematic review of published trials: long-term safety of topical corticosteroids and topical calcineurin inhibitors in pediatric patients with atopic dermatitis. *BMC Pediatr*. 2016 Jun 7; 16:75.
27. Silverberg JI, Toth D, Bieber T, et al.; ECZTRA 3 study investigators. Tralokinumab plus topical corticosteroids for the treatment of moderate-to-severe atopic dermatitis: results from the double-blind, randomized, multicentre, placebo-controlled phase III ECZTRA 3 trial. *Br J Dermatol*. 2021 Mar;184(3):450-463.
28. Slater NA and Morrell DS. Systemic therapy of childhood atopic dermatitis. *Clin Dermatol*. 2015 May-Jun;33(3):289-99. Epub 2014 Dec 8.
29. Tsakok T and Flohr C. Methotrexate vs. ciclosporin in the treatment of severe atopic dermatitis in children: a critical appraisal. *Br J Dermatol*. 2014 Mar;170(3):496-8; discussion 498-9.
30. Totri CR, Eichenfield LF, Logan K, et al. Prescribing practices for systemic agents in the treatment of severe pediatric atopic dermatitis in the US and Canada: The PeDRA TREAT survey. *J Am Acad Dermatol*. 2017 Feb;76(2):281-285. Epub 2016 Nov 14.
31. Wollenberg A, Blauvelt A, Guttman-Yassky E, et al. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicentre, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). *Br J Dermatol* 2021; 184(3):437-449.
32. Yang EJ, Sekhon S, Sanchez IM, et al. Recent Developments in Atopic Dermatitis. *Pediatrics*. 2018 Oct;142(4). pii: e20181102.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 02/11/26.

GUIDELINE UPDATE INFORMATION:

03/15/26	New Medical Coverage Guideline.
----------	---------------------------------