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Subject: Lebrikizumab-lbkz (Ebglyss) Injection

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DESCRIPTION:

Lebrikizumab-lbkz (Ebglyss) is an interleukin-13 (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) in December 2021. 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. IL-13 is a naturally occurring cytokine of the Type 2 immune response. Lebrikizumab 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 phosphodiesterase (PDE)-4 inhibitors (e.g., crisaborole) [mild to moderate AD]
- Topical Janus kinase (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

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 Pruritis 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) **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 lebrikizumab (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with lebrikizumab (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. Lebrikizumab 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 lebrikizumab

II. The prescriber has provided information in support of using lebrikizumab for the member's age for the requested indication

2. If the member has a 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 lebrikizumab

   AND

   b. 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 for AD), **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 Ebglyss

5. The member will **NOT** be using lebrikizumab 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 [Velsipity (etrasimod) and Zeposia (ozanimod)]

6. **ONE** of the following ("a", "b", "c", or "d"):
   a. The requested quantity (dose) does **NOT** exceed the following:

      - 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 – **BOTH** of the following:

      - 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)
      - 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 for the requested indication, **AND** there is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength size that does **NOT** exceed the program quantity limit

d. The requested indication does **NOT** have a maximum FDA labeled dose, **AND** there is support for therapy with a higher dose for the requested indication

Approval duration: 6 months (loading doses approved for 16 weeks, then maintenance dose approved for the remainder of the 6 months)

Table

Indications and Specific Criteria	
Indication	**Specific Criteria**
Moderate-to-severe atopic dermatitis (AD)	When **BOTH** of the following are met ("1" and "2"): 1. **ONE** of the following ("a", "b", "c", or "d"): a. The member has at least 10% body surface area involvement **OR** b. 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** c. The member has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR** d. The member has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND** 2. **EITHER** of the following ("a" or "b"): a. **BOTH** of the following ("i" and "ii"): i. **ONE** of the following: • 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 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 **AND** ii. **ONE** of the following: • 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 **OR** • The member has an intolerance or hypersensitivity to **ONE** topical calcineurin inhibitor used in the treatment of AD **OR** • The member has an FDA labeled contraindication to **ALL** topical calcineurin inhibitors used in the treatment of AD **OR** 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 labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of lebrikizumab-lbkz (Ebglyss) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "7"):

1. An authorization or reauthorization for lebrikizumab 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 lebrikizumab
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 lebrikizumab
4. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist, allergist, immunologist for AD), **OR** the prescriber has consulted with a specialist in the area of the member's diagnosis
5. The member does **NOT** have any FDA labeled contraindications to Ebglyss
6. The member will **NOT** be using lebrikizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo 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)]

7. **ONE** of the following ("a", "b", "c", or "d"):
    a. The requested quantity (dose) does **NOT** exceed the following:
        - 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 – **BOTH** of the following:
        - 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)
        - 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 for the requested indication, **AND** there is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength size that does **NOT** exceed the program quantity limit
    d. The requested indication does **NOT** have a maximum FDA labeled dose, **AND** there is support for therapy with a higher dose for the requested indication

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

- 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

- 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

- 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

- None

Contraindications

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

Precautions/Warnings

- **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

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

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 ≥50%
- EASI 75 - a percentage improvement of EASI score from baseline that is ≥75%
- EASI 90 - a percentage improvement of EASI score from baseline that is ≥90%

Pruritus – itching

RELATED GUIDELINES:

Abrocitinib (Cibinqo), 09-J4000-27

Dupilumab (Dupixent), 09-J2000-80

Nemolizumab (Nemluvio), 09-J4000-99

Tralokinumab (Adbry), 09-J4000-20

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 02/11/26.

GUIDELINE UPDATE INFORMATION:

01/01/25	New Medical Coverage Guideline.
07/01/25	Revision to guidelines consisting of updates to the description section, position statement, and related guidelines. The step through other biologic agents for atopic dermatitis was removed.
01/01/26	Review and revision to guidelines consisting of update to the description section, position statement, and references
03/15/26	Retire MCG. Ebglyss added to the IL-13 Antagonists MCG.