Lebrikizumab-lbkz (EBGLYSS) in Atopic Dermatitis
National Drug Mini-Monograph

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VA Pharmacy Benefits Management Services and National Formulary Committee

The purpose of VA PBM Services drug monographs is to provide a focused drug review for making formulary decisions. The Product Information or other resources should be consulted for detailed and most current drug information.

Abbreviations: AAAAI / ACAAI JTF, American Academy of Allergy, Asthma and Immunology / American College of Allergy, Asthma and Immunology Joint Task Force; AC, active-controlled; CO, crossover; DB, double-blind; DLQI, Dermatology Life Quality Instrument; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; MC, multicenter; MN, multinational; PC, placebo-controlled; POEM, Patient Oriented Eczema Measure; PP-NRS, peak pruritus numeric rating scale; Q, GRADE quality of evidence; RCT, randomized clinical trial; TCS, topical corticosteroids

FDA APPROVAL INFORMATION[1]	
Description / MOA	Interleukin-13 (IL-13) antagonist; fully human IgG4-kappa monoclonal antibody that binds to IL-13 and selectively inhibits IL-13 signaling via the IL-4 receptor alpha / IL-13 receptor alpha-1 pathway. Its mechanism differs from that of tralokinumab-ldrm, which competitively inhibits the binding of IL-13 to the IL-13 receptor alpha-1 and IL-13 receptor alpha-2, a decoy receptor involved in regulating IL-13.
Indication Under Review	Treatment of adults with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Can be used with or without topical corticosteroids (TCS).
Dosage Regimen	*Induction*: 500 mg (two 250-mg injections) SC at Weeks 0 and 2, then 250 mg (one injection) SC every 2 weeks until Week 16 or later, when adequate clinical response is achieved. *Maintenance*: 250 mg SC every 4 weeks
Dosage Forms Under Review	Injection: 250 mg/2 mL in single-dose prefilled pen or syringe
Pretreatment Procedures	□ Complete all age-appropriate vaccinations according to current guidelines. Avoid use of live vaccines immediately before and during treatment. □ Treat any pre-existing parasitic (helminth) infections □ There are otherwise no recommendations for infection, tuberculosis, or hepatitis B virus screening.
Treatment Monitoring	□ Hypersensitivity reactions □ Adverse reactions including conjunctivitis and keratitis, injection site reactions, and herpes zoster □ Laboratory tests: No recommendations

EFFICACY CONSIDERATIONS	
Monotherapy Trials	**ADvocate 1 and ADvocate 2: Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis[1,2,3]** **Efficacy and safety of lebrikizumab in moderate-to-severe atopic dermatitis: 52-week results of two randomized double-blinded placebo-controlled phase III trials[4]**
Design	52-week multinational, double-blind, placebo-controlled, phase 3 randomized clinical trials (2:1) with 16-week induction phase and 36-week re-randomized maintenance phase. Week-16 responders (achieved primary endpoint or had 75% improvement in the Eczema Area and Severity Index [EASI] or EASI-75) who did not receive rescue therapy were re-randomized 2:2:1 to 36 weeks of maintenance therapy with lebrikizumab 250 mg SC every 2 weeks or every 4 weeks or placebo (i.e., lebrikizumab withdrawal). *Primary Endpoints*: Percentage of patients who achieved an Investigational Global Assessment (IGA) score of 0 (Clear) or 1 (Almost Clear) and ≥2-point reduction / improvement from baseline at Week 16 (IGA Success)
Population	*Inclusion Criteria:* Adults (≥18 years) and adolescents (12 to <18 years, ≥40 kg) with moderate to severe AD, Eczema Area and Severity Index (EASI) score ≥16 (scale: 0 to 72), IGA ≥3 (scale: 0 / Clear to 4 / Severe Disease), affected body surface area ≥10%, chronic AD for ≥1 year; topical treatment was inadequate or inadvisable. *Exclusion Criteria:* Previous treatment with dupilumab, tralokinumab, or lebrikizumab. *Baseline Characteristics, ADvocate 1 (N = 424) | ADvocate 2 (N = 445), respectively*: Mean age 36|36 years; age range ≥18 years old 87%|88%; male 51%|50%; White 68%|59%; previous use of systemic treatment 56%|56%; affected body surface area 47%|46%

Interventions

Induction: Lebrikizumab 500 mg SC at Weeks 0 and 2, then 250 mg SC every 2 weeks through Week 16

Maintenance, Responders Only: 250 mg every 2 weeks or 250 mg every 4 weeks for an additional 36 weeks

Comparator

Placebo

Co-therapies

Not allowed except as rescue therapy: topical treatments (topical corticosteroids) and systemic treatments (e.g., oral corticosteroids, cyclosporine, dupilumab, tralokinumab, phototherapy) through Week 16

Results

Table 1. Induction Efficacy at Week 16

Outcome	Trial	LBKZ	Placebo	RR (95% CI)	ARD (95% CI)	Q
IGA Success, n/N (%)	ADvocate 1	122/283 (43)	18/141 (13)	3.4 (2.2, 5.3)	30 (22, 38)	M[α]
	ADvocate 2	93/281 (33)	16/146 (11)	3.0 (1.8, 4.9)	22 (14, 30)	M[α]
EASI-90, n/N (%)	ADvocate 1	108/283 (38)	13/141 (9)	4.1 (2.4, 7.1)	29 (21, 36)	M[α]
	ADvocate 2	87/281 (31)	15/146 (10)	3.0 (1.8, 5.0)	21 (13, 28)	M[α]
Worst Daily Pruritus NRS-4,[a] n/N (%)	ADvocate 1	121/263 (46)	17/130 (13)	3.5 (2.2, 5.6)	33 (25, 41)	M[α]
	ADvocate 2	101/253 (40)	16/134 (12)	3.3 (2.1, 5.4)	28 (20, 37)	M[α]
Sleep-Loss-2, n/N (%)[b]	ADvocate 1	110/283 (39)	7/141 (5)	7.8 (3.8, 16.4)	35 (26, 43)	M[α]
	ADvocate 2	79/281 (28)	12/146 (8)	3.4 (1.9, 6.1)	19 (10, 28)	M[α]

a Subgroup with baseline Pruritus NRS score ≥4. A minimal clinically important difference is a 2–4-point change.

b Subgroup with baseline Sleep-Loss score of ≥2 at baseline. Sleep-Loss-2 refers to reduction / improvement of ≥2 points on the Sleep-Loss scale, measuring sleep interference related to itching.

[α] Downgraded for imprecision (optimal information size not met; wide CIs)

Table 2. Maintenance Efficacy at Week 52 in Week-16 Responders, IGA Success

Trial	Data	LBKZ 250 mg Q2W	LBKZ 250 mg Q4W	Placebo (LBKZ WD)	Q
ADvocate 1	**n/N (%)**	**34/45 (76)**	**33/45 (74)**	**10/22 (47)**	M[α]
	RR (95% CI)	1.7 (1.0, 2.7)	1.6 (1.0, 2.6)		
	ARD (95% CI)	30 (22, 38)	29 (3, 52)		
ADvocate 2	**n/N (%)**	**21/32 (65)**	**26/32 (81)**	**8/16 (50)**	M[α]
	RR (95% CI)	1.3 (0.8, 2.3)	1.6 (1.0, 2.7)		
	ARD (95% CI)	15 (14, 45)	31 (3, 59)		

WD, withdrawal

[α] Downgraded for imprecision (optimal information size not met; wide CIs)

Significant treatment difference in Pruritus NRS-4 response at Week 2: Observed in ADvocate 1 but not in ADvocate 2.

Subgroup Analyses: No treatment differences in IGA Success response were seen among subgroups.

Authors' Conclusions

Lebrikizumab improved signs and symptoms of moderate to severe atopic dermatitis in adults and adolescents.

Concomitant Therapy Trial

Efficacy and Safety of Lebrikizumab in Combination With Topical Corticosteroids in Adolescents and Adults With Moderate-to-Severe Atopic Dermatitis: A Randomized Clinical Trial (ADhere)[5]

Design

16-week multinational, double-blind, placebo-controlled phase 3 RCT (2:1), stratified by geographic region, age group, and disease severity

Primary Efficacy Endpoint: Percentage of patients with IGA-0/1-2

Population

211 adults and adolescents (≥12 to <18 years, ≥40 kg) with moderate to severe AD

Baseline Characteristics (N = 228): Mean age 37.2 years; 51.2% men; 61.4% White; 14.7% Asian, 13.3% Black / African American; 39.3% body surface area affected; 48.5% prior systemic therapy; 30.8% prior systemic corticosteroid; 13.7% dupilumab

Intervention

Induction Phase: Lebrikizumab 500 mg SC at Weeks 0 and 2, then 250 mg SC every 2 weeks through Week 16 (administered in clinic) plus a low-potency corticosteroid (hydrocortisone cream 1%) or mid-potency topical corticosteroids (triamcinolone acetonide cream 0.1%)

Comparator

Placebo plus TCS

Other Allowed Therapies

Topical calcineurin inhibitors for sensitive areas only (e.g., face, neck, intertriginous, and genital)

Results

Results showed a significant benefit with lebrikizumab + TCS over placebo + TCS, albeit with smaller effects than those seen in the monotherapy trials.

Table 3. Efficacy at Week 16

Outcome	LBKZ 250 mg Q2W + TCS	Placebo + TCS	RR (95% CI)	ARD (95% CI)	Q
IGA Success, n/N (%)	60/145 (41.2)	15/66 (22.1)	1.8 (1.12, 3.96)	18.3 (5.1, 31.5)	M[α]
EASI-90 n/N (%)	60/145 (41.2)	14/66 (21.7)	2.0 (1.18, 3.23)	18.9 (6.1, 31.7)	M[α]
Pruritus NRS-4 n/N (%)	73/145 (50.6)	21/66 (31.9)	1.6 (1.07, 2.33)	19.2 (4.3, 34.1)	M[α]
DLQI-4 n/N (%)	112/145 (77.4)	39/66 (58.7)	1.3 (1.05, 1.63)	17.2 (0.1, 34.3)	M[α]

[α] Downgraded for imprecision (optimal information size not met, wide confidence intervals)

- Onset / Earliest statistically significant difference: Week 8.
- Subgroup Analyses: Greater risk difference in males for EASI-75 and EASI-90.
- TCS / TCI-free days: NSD at Week 16. A statistically significant difference (SSD) was seen at Weeks 6, 8, and 10.
- TCS / TCI-free by end of study: 50% vs Not reached for LBKZ + TCS vs placebo + TCS.

Authors' Conclusions	Lebrikizumab + TCS, relative to placebo + TCS, achieved significant improvements in the signs and symptoms of moderate-to-severe AD in adolescents and adults. The benefit-risk profile of lebrikizumab + TCS was consistent with previous lebrikizumab studies in patients with AD. The results suggest that lebrikizumab + TCS may be an effective treatment option for adults and adolescents with moderate-to-severe AD.
Phase 2 Trials	Phase 2b multicenter RCT[6]
Other Ongoing Trials	ADjoin: long-term extension study
Indirect Comparisons from Network Meta-analyses	• A living systematic review / network meta-analysis (K = 97 trials; N = 24,679) concluded that there was moderate- to high-certainty evidence that lebrikizumab showed no important differences vs dupilumab in changes from baseline to Week 16 in EASI, Patient Oriented Eczema Measure (POEM), DLQI, and peak pruritus numeric rating scale (PP-NRS).[7] Dupilumab had higher point-estimate odds of achieving EASI-90 (OR 1.5; 95% CrI, 1.1, 2.2) and IGA success (1.3; 0.9, 1.9); however, the confidence intervals included values close to or less than 1.0. There was insufficient data to interpret indirect safety comparisons. • In an unanchored matching-adjusted indirect comparison using individual patient data, lebrikizumab showed a greater likelihood of maintaining IGA-0/1 from Weeks 16 to 52 than dupilumab (RR 1.3; 95% CI 1.02, 1.74).[8] The two treatments were similar in EASI-75 and adverse event rates. Sanofi and Regeneron (manufacturers of dupilumab) criticized the methodology used for the indirect treatment comparison and concluded that the results were "unsuitable for decision-making."[9] • Another network meta-analysis assessed lebrikizumab (250 mg Q2W) as being among the intermediate (inferior) effective agents for AD severity, patient-reported AD severity, itch, and eczema-related quality of life; among the most effective for improving sleep; and possibly among the intermediate harmful for AD flares, any adverse event, and serious adverse events.[10]

SAFETY CONSIDERATIONS	
Boxed Warnings	None
Contraindications	Hypersensitivity
Other Warnings	Hypersensitivity, conjunctivitis and keratitis, parasitic (helminth) infections, avoid live vaccines during treatment
Most Common AEs	≥1%: Conjunctivitis, injection site reactions, herpes zoster.
Drug Interactions	Not studied
Renal Impairment	No pharmacokinetic studies
Hepatic Impairment	No pharmacokinetic studies
Pregnancy	*Humans*: Insufficient data. May be transmitted to a developing fetus. Human IgG antibody is transported across the placenta as pregnancy progresses, peaking in the third trimester. *Animals*: No effects on embryo-fetal development were observed in monkey studies.
Lactation	Insufficient data. Endogenous IgG and monoclonal antibodies are transferred in human milk. Effects from local gastrointestinal exposure and limited systemic exposure to the drug on the breastfed infant are unknown. Weigh risks vs benefits.

PBM Notes

For reference, the incidences of conjunctivitis during the induction phase of AD trials with lebrikizumab-lbkz and other biologics for AD are shown in Table 4.

Table 4. Rates of Conjunctivitis with AD Biologics

	Monotherapy		Combotherapy with TCS	
Drug	**Drug**	**Placebo**	**Drug**	**Placebo**
Dupilumab	51/ 529 (10%)	12/517 (2%)	10/110 (9%)	15/315 (5%)
Tralokinumab-ldrm	88/1180 (8%)	12/388 (3%)	33/243 (14%)	6/123 (5%)
Lebrikizumab-lbkz	61/ 638 (10%)	10/338 (3%)	7/145 (5%)	0/ 66 (0%)
Nemolizumab-ilto	Not reported as an AE		Not reported as an AE	

Sources: [11,12,13]

OTHER CONSIDERATIONS

Adequate Therapeutic Trial

16 weeks based on length of induction phase and time point of maximal IGA success rates.

FDA Comments

The less-frequent dose of Q4W was recommended for maintenance since the lebrikizumab 250 mg Q2W and Q4W dosage regimens maintained similar responses with similar immunogenicity and safety, and Q4W reduces injection burden and provides a convenient dosing frequency.

Uncertainties

Efficacy and safety of lebrikizumab-lbkz in patients with inadequate response to dupilumab- or tralokinumab.

Whether higher weight (≥100 kg) reduces effect size relative to lower weight (<100 kg) is uncertain. Sample sizes were small and therefore limited the interpretation of the data.[3]

THERAPEUTIC ALTERNATIVES FOR MODERATE-TO-SEVERE ATOPIC DERMATITIS AND THEIR PLACE IN THERAPY

Table 4. Place in Therapy of Therapeutic Alternatives

DRUG	VANF	CFU	FDA (ADULT INDICATIONS)	AAD GUIDELINES (2024)[14]	2023 AAAAI/ACAAI JTFPP GUIDELINES[15]
Anti-Interleukin-4/13					
Dupilumab (DUPIXENT)	No	Moderate-to-severe AD refractory to ≥2 classes of topical therapies for ≥12 weeks total unless medically inadvisable or not tolerated. If patient weighs <100 kg, consider tralokinumab prior to dupilumab	Treatment of adults with moderate-to-severe AD not adequately controlled with topical prescription therapies or when those therapies are not advisable. Can be used with or without TCS.	Strong recommendation (moderate certainty evidence)	Recommend adding; consider if refractory, intolerant, or unable to use mid-to-high–potency topical treatment (strong in favor, high certainty evidence)
Anti-IL-13					
Tralokinumab-ldrm (ADBRY)	No	Same as for dupilumab	Same as for dupilumab	Strong recommendation (moderate certainty evidence)	Same as for dupilumab
Lebrikizumab-lbkz (EBGLYSS)	TBD	TBD	Same as for dupilumab	Not mentioned	Not mentioned
Anti-IL-31					
Nemolizumab-ilto (NEMLUVIO)	TBD	TBD	Treatment of adults with moderate-to-severe AD in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies	Not mentioned	Not mentioned
Janus Kinase Inhibitors					
Abrocitinib (CIBINQO)	No	Prior dupilumab or tralokinumab-ldrm (NO response after 12 wks or inadequate response after 16 wks) unless contraindicated, not tolerated, or otherwise medically inadvisable	Treatment of adults with refractory, moderate-to-severe AD whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Limitation of Use: Not recommended for use in combination with other JAKis, biologic immunomodulators, or with other immunosuppressants.	Strong recommendation (moderate certainty evidence)	Suggest adding a JAKi; consider if refractory, intolerant or unable to use mid-to-high–potency topical treatment and systemic treatment inclusive of a biologic recommended above (conditional in favor; low certainty evidence)
Upadacitinib (RINVOQ)	No	Same as for abrocitinib	Same as for abrocitinib	Strong recommendation (moderate certainty evidence)	Same as for abrocitinib
Baricitinib (	No	NA	Off label	Strong recommendation (moderate certainty evidence)	Same as for abrocitinib. Recommend against using dose of 1 mg daily.
Antimetabolite					
Methotrexate	Yes	NA	Off label	Conditional recommendation (low certainty evidence)	Suggest against adding (conditional against, low certainty evidence)

DRUG	VANF	CFU	FDA (ADULT INDICATIONS)	AAD GUIDELINES (2024)[14]	2023 AAAAI/ACAAI JTFPP GUIDELINES[15]
Immunosuppressants					
Corticosteroids, Systemic	Yes	NA	Anti-inflammatory or immunosuppressive agent for a variety of certain conditions including dermatologic	Conditional recommendation against; use should be reserved exclusively for acute, severe exacerbations and short-term bridge therapy to other systemic, corticosteroid-sparing therapy (low certainty evidence)	Suggest against systemic corticosteroids for all patients with AD (conditional against, low certainty evidence)
Azathioprine	Yes	NA	Off label	Conditional recommendation (low certainty evidence)	Suggest against adding (conditional against, low certainty evidence)
Cyclosporine	Yes	NA	Off label	Conditional recommendation for limited-term use with proper monitoring (low certainty evidence)	Suggest adding; shared decision-making should determine whether to start therapy at high dose (5 mg/kg) or low dose (3 mg/kg) (conditional in favor, low certainty evidence)
Mycophenolate mofetil	Yes	NA	Off label	Conditional recommendation (very low certainty evidence)	Suggest against adding (conditional against, low certainty evidence)

POTENTIAL PLACE IN THERAPY	
Evidence Summary	• There were no active-controlled trials to inform the place in therapy of lebrikizumab-lbkz. Moderate quality evidence from the two phase 3 trials, ADvocate 1 and ADvocate 2, showed that lebrikizumab-lbkz monotherapy produced moderate to large improvements in lesion inflammation, itch, and measures of sleep in adults with moderate to severe AD for which topical therapy was inadequate or inadvisable. Maintenance therapy showed a durable response up to 52 weeks. Combination lebrikizumab + TCS had a small benefit over placebo + TCS in a population with (48%) or without prior exposure to systemic therapies. Evidence is lacking on the effects of lebrikizumab-ldrm after failure of targeted systemic therapies and its long-term safety beyond 52 weeks. • Compared with dupilumab and tralokinumab-ldrm at *standard* doses, lebrikizumab-lbkz therapy costs about 8 times more for induction but 20% to 30% less for maintenance therapy. • Use of tralokinumab-ldrm (300 mg SC every 4 weeks, an alternative dosage for a subgroup of patients) and nemolizumab-ilto (30 mg every 8 weeks, the recommended standard dose) may be less costly than lebrikizumab-lbkz as maintenance therapy. • Study populations consisted primarily of middle-aged white males. It is uncertain to what extent the results can be extrapolated to the VHA patient population.
Potential VHA Place in Therapy	• Lebrikizumab-lbkz may be used in the treatment of patients with moderate-to-severe AD who are refractory to ≥ 2 classes of topical therapies for ≥ 4 weeks total unless they are medically inadvisable or not tolerated. Lebrikizumab-lbkz may be considered as an alternative to dupilumab and tralokinumab-ldrm based on its favorable efficacy-safety-cost profile. • Although lebrikizumab was highly effective as monotherapy, guidelines recommend the addition of biologics if there is refractoriness, intolerance, or inability to use mid- to high-potency topical therapies.[15]

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