DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Immunologicals – Ebglyss Drug Quantity Management Policy – Per Days
- Ebglyss® (lebrikizumab-lbkz subcutaneous injection – Eli Lilly)

REVIEW DATE: 09/25/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Ebglyss, an interleukin (IL)-13 antagonist, is indicated for the treatment of moderate to severe **atopic dermatitis** in adults and pediatric patients ≥ 12 years of age who weigh ≥ 40 kg whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.[1] Ebglyss may be used with or without topical corticosteroids (TCSs).

Dosing

The recommended initial dose of Ebglyss is 500 mg subcutaneous (SC) [two 250 mg injections] at Weeks 0 and 2, followed by 250 mg SC once every 2 weeks (Q2W) until Week 16 or later, when adequate clinical response is achieved.[1] The maintenance dose is 250 mg SC once every 4 weeks (Q4W).

Availability

Ebglyss is available as a single-dose prefilled pens and syringes, each containing 250 mg/2 mL of solution.

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential dose escalation of Ebglyss. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Ebglyss® (lebrikizumab-lbkz subcutaneous injection)	250 mg/2 mL pens	4 mL (2 pens)	12 mL (6 pens)
	250 mg/2 mL syringes	4 mL (2 syringes)	12 mL (6 syringes)

Immunologicals – Ebglyss Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Ebglyss 250 mg/2 mL pens and prefilled syringes

1. If the patient is initiating therapy at induction dosing for atopic dermatitis, as verified by the absence of claims for Ebglyss in the past 130 days, approve a one-time override for 8 mL (4 pens or syringes) at retail or 16 mL (8 pens or syringes) home delivery.
Note: The retail override quantity of 8 mL (4 pens/syringes) provides a quantity sufficient for the initial 500 mg loading doses at Weeks 0 and 2. The home delivery override quantity of 16 mL (8 pens/syringes) provides a quantity sufficient for the initial 500 mg loading doses at Weeks 0 and 2, followed by 250 mg once every 2 weeks for a total of 84 days of treatment.

REFERENCES

1. Ebglyss® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; September 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/25/2024