Prior Authorization Criteria

EBGLYSS® (lebrikizumab-lbkz) PA CRITERIA:

EBGLYSS® (lebrikizumab-lbkz) is an interleukin-13 antagonist indicated to treat adults and pediatric patients ages 12 years 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.

Submission of medical records or prescription claims documenting the following requirements for the indications below is required upon request. Trials will be based on prescription claims and use of medication samples will NOT be accepted as medical justification.

EBGLYSS® may be approved based on ALL of the following criteria:

INITIAL AUTHORIZATION: (will be issued for 6 months)

1. Diagnosis of moderate to severe chronic atopic dermatitis;

-AND-

2. Affected body surface area is greater than or equal to 10%;

-AND-

3. Age and weight of patient is within the requirements as recommended by the FDA label;

-AND-

4. Prescribed by or in consultation with an allergist, dermatologist, or immunologist;

-AND-

5. Patient is **not** receiving Ebglyss in combination with another biologic medication or JAK inhibitor for the treatment of atopic dermatitis [e.g., Enbrel (etanercept), Remicade/Inflectra (infliximab), Xolair (omalizumab), Rituxan (rituximab), Adbry (tralokinumab-ldrm), Dupixent (dupilumab), Opzelura (topical ruxolitinib)];

-AND-

6. Patient meets ONE of the following four scenarios:

A) **For <u>moderate</u> atopic dermatitis: BOTH of the following:**

- One preferred medium to very-high potency topical corticosteroid ≥ 2 week trial (1 claim in last 90 days);

-and-

- **Either** one topical calcineurin inhibitor [Elidel/pimecrolimus or Protopic/tacrolimus] -**or**- Eucrisa (crisaborole) used for ≥ 4 week trial (1 claim in the last 90 days);

-OR-

B) **For <u>severe</u> atopic dermatitis: BOTH of the following:**

- One preferred medium to very-high potency topical corticosteroid ≥ 2 week trial (1 claim in the last 90 days);

-and-

- One topical calcineurin inhibitor [Elidel /pimecrolimus or Protopic/tacrolimus] used for ≥ 4 week trial (1 claim in the last 90 days);

-OR-

C) Prescriber provides detailed clinical justification to why topical therapies are inadvisable with supporting documentation (e.g., failure, intolerance, or contraindication to scenarios outlined in 6A or 6B);

-OR-

D) Patient is currently on Ebglyss therapy (not including the use of samples);

-AND-

7. Prescribed dose does not exceed the following:
    - Initial dose: 500 mg (2 pens) at Week 0 and Week 2, followed by 250 mg every 2 weeks until Week 16 or later, when adequate clinical response is attained
    - Maintenance dose: 250 mg (one pen) every 4 weeks

<u>REAUTHORIZATION</u>: (will be issued for 12 months)

1. Patient continues to meet initial authorization criteria; **AND**

2. Prescribed dose does not exceed a maintenance dose of 250 mg every 4 weeks; **AND**

3. Positive clinical response to Ebglyss therapy (e.g., reduction in body surface area, reduction in pruritus severity).