Prior Authorization Criteria

Adbry® (tralokinumab-ldrm) PA Criteria FOR ATOPIC DERMATITIS:

Adbry® (tralokinumab-ldrm) is an interleukin-13 antagonist indicated for the treatment of moderate to severe atopic dermatitis in patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

- *Adbry can be used with or without topical corticosteroids.*

Submission of medical records or prescription claims history 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.

Adbry® FOR ATOPIC DERMATITIS 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 of patient is within the age range 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 Adbry 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), 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 Adbry therapy (not including the use of samples);

-AND-

7. Prescribed dose does not exceed the following:
    - Initial (one-time) dose: 600 mg
    - Maintenance dose: 300 mg every other week

<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 300 mg every other week or monthly; **AND**

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