

tralokinumab-ldrm (ADBRY)

Diagnosis Considered for Coverage:

- Atopic dermatitis (AD)

Coverage Criteria:

For diagnosis of moderate to severe atopic dermatitis, approve if:

INITIAL AUTHORIZATION

- Age is consistent with the FDA approved indication,
and
- Prescribed by or in consultation with a dermatologist, allergist, or immunologist, **and**
- Diagnosis of moderate to severe atopic dermatitis with at least one of the following:
 - a. Investigator's Global Assessment (IGA) score of 3-4,
 - b. Eczema Area and Severity Index (EASI) score of at least 16,
 - c. Body surface area (BSA) of at least 10%,
 - d. Severity Scoring of Atopic Dermatitis Index (SCORAD) score of at least 25,**and**
- Inadequate response or intolerable side effect to TWO of the following, or contraindication to ALL of the following:
 - Medium, high, or very high potency topical corticosteroid or
 - Topical calcineurin inhibitor [e.g. tacrolimus (Protopic) or topical Elidel (pimecrolimus)], or
 - Phototherapy, or
 - Systemic immunomodulating agents (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine),**and**
- Inadequate response or intolerable side effect with two preferred agents (e.g., Dupixent, Rinvoq), or contraindication to all preferred agents,
and
- Not used in combination with other JAK inhibitors (e.g. Rinvoq, Cibinqo), biologic immunomodulators (e.g. Dupixent), or with other immunosuppressants (e.g. methotrexate, azathioprine, mycophenolate mofetil, cyclosporine),
and
- Dose does not exceed FDA label maximum.

Coverage Duration: 16 weeks

REAUTHORIZATION

- Patient has clinical response, **and**
- Not used in combination with other JAK inhibitors (e.g. Rinvoq, Cibinqo), biologic immunomodulators (e.g. Dupixent), or with other immunosuppressants (e.g. methotrexate, azathioprine, mycophenolate mofetil, cyclosporine), **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: one year

Coverage Duration: See coverage criteria.

Effective: 01/03/2024