GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet ALL of the following criteria?
   - Patient has one of the following: minimum body surface area (BSA) involvement of at least 10%, Eczema Area and Severity Index (EASI) score of at least 16, or Physician Global Assessment (PGA) score of at least 3.
   - Prescribed by or in consultation with a dermatologist or allergist/immunologist.
   - Patient is 18 years of age or older.
   - Documentation of inadequate response or contraindication to one of the following: topical corticosteroids, topical calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] or topical PDE-4 inhibitors [e.g., Eucrisa (crisaborole)].
   - History of failure, contraindication or intolerance to NBUVB phototherapy (at home or in clinic).
   - History of contraindication to, or patient has tried and failed (at least 1 month trial), 2 of the following systemic therapies:
     - Azathioprine
     - Cyclosporine
     - Methotrexate
     - Mycophenolate

If yes, please enter TWO approvals by HICL as follows:
   - FIRST APPROVAL: approve one fill with a quantity limit of #4mL (#2 300mg/2mL syringes)
   - SECOND APPROVAL: approve for 6 months with a quantity limit of #4mL (#2 300mg/2mL syringes) per 28 days (please enter a start date 2 WEEKS AFTER the START date of the first approval)

APPROVAL TEXT: Renewal requires documentation of one of the following:
   - Patient has experienced or maintained a reduction in body surface area (BSA) involvement of at least 20% from baseline OR
   - Patient has achieved or maintained clear or minimal disease (Physician Global Assessment equal to 0 or 1) OR
   - Patient has experienced or maintained a decrease in EASI (Eczema Area and Severity Index Score) of at least 50%

If no, do not approve.
DENIALTEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named DUPILIMAB (Dupixent) requires a diagnosis of moderate to severe atopic dermatitis. In addition, all of the following criteria must be met:

- Patient has one of the following: minimum body surface area (BSA) involvement of at least 10%, Eczema Area and Severity Index (EASI) score of at least 16, or Physician Global Assessment (PGA) score of at least 3.
- Prescribed by or in consultation with a dermatologist or allergist/immunologist.
- Patient is 18 years of age or older.
- Documentation of inadequate response or contraindication to two of the following: topical corticosteroids, topical calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], or topical PDE-4 inhibitors [e.g., Eucrisa (crisaborole)]
- History of failure, contraindication or intolerance to NBUVB phototherapy (at home or in clinic).
- History of contraindication to, or patient has tried and failed (at least 1 month trial), 2 of the following systemic therapies:
  - Azathioprine
  - Cyclosporine
  - Methotrexate
  - Mycophenolate

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet the following criterion?
   - Documentation of one of the following:
     o Patient has experienced or maintained a reduction in body surface area (BSA) involvement of at least 20% from baseline OR
     o Patient has experienced or maintained clear or minimal disease (Physician Global Assessment equal to 0 or 1) OR
     o Patient has experienced or maintained a decrease in Eczema Area and Severity Index (EASI) Score of at least 50%

If yes, approve for 12 months by HICL with a quantity limit of #4mL (#2 300mg/2mL syringes) per 28 days.
If no, do not approve.

DENIAL TEXT: The guideline named DUPILIMAB (Dupixent) renewal requires a diagnosis of moderate to severe atopic dermatitis. In addition, the following criterion must be met:

- Documentation of one of the following:
  o Patient has experienced or maintained a reduction in body surface area (BSA) involvement of at least 20% from baseline OR
  o Patient has experienced or maintained clear or minimal disease (Physician Global Assessment equal to 0 or 1) OR
  o Patient has experienced or maintained a decrease in Eczema Area and Severity Index (EASI) Score of at least 50%

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DUPILUMAB

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for (Dupixent) dupilumab.

FDA APPROVED INDICATIONS
Dupixent is indicated for the treatment of adult patients with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

DOSSING
The recommended dose is an initial subcutaneous dose of 600mg (two 300mg injections in different sites), followed by 300mg subcutaneously given every other week.

DOSAGE FORMS AND STRENGTHS
Dupixent is supplied as 300mg/2mL single dose prefilled syringes.

REFERENCES