Authorization guidelines

For Moderate to Severe Atopic Dermatitis, may be authorized when all the following are met:

A. Member is 18 years of age or older
B. Diagnosis of moderate to severe atopic dermatitis and one of the following:
   1. Member has baseline evaluation of condition using Patient-Oriented Eczema Measure (POEM) with a score greater than or equal to 8 or an Investigator’s Global Assessment (IGA) score greater than or equal to 3. (https://jamanetwork.com/data/Journals/DERM/11776/dea40003f1.png)
   OR
   2. Member has a high involvement of body surface area (BSA) or involvement of highly visible areas or areas that are important for function (neck, face, genitals, palms, soles)
C. Prescribed by, or in consultation with, a dermatologist, allergist or immunologist
D. Patient had an inadequate response or intolerable side effects to all of the following:
   1. Two preferred (medium to very high potency) topical corticosteroids (e.g. triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide).
   2. Note: for sensitive areas, such as the face, only one preferred low potency topical corticosteroid is required.
   3. Topical tacrolimus
   4. At least one oral systemic therapy such as methotrexate (MTX), cyclosporine, azathioprine or mycophenolate

For Moderate to Severe Asthma, may be authorized when all of the following are met:

A. Member is 12 years of age or older
B. Documented diagnosis of moderate to severe asthma with one of the following (submission of medical records required):
   1. Eosinophilic phenotype, with pretreatment eosinophil count greater than or equal to 150/microL
   2. Corticosteroid dependent asthma (has received greater than or equal to 5 mg/day oral prednisone or equivalent per day)
C. Prescribed by, or in consultation with a pulmonologist, allergist, or immunologist
D. Dupixent will be used as add on therapy to a medium or high dose Inhaled Corticosteroid (ICS), plus one additional controller (for example, Long-Acting Beta Agonist (LABA), or Long-Acting Muscarinic Antagonist (LAMA) etc.
E. Member has been compliant with medium to high dose Inhaled Corticosteroids (ICS) plus a Long-Acting Beta Agonist (LABA), Long-Acting Muscarinic Antagonist (LAMA), or other controller for at least three months, and remains symptomatic
F. Asthma symptoms are uncontrolled, as defined by one of the following:
   1. Use of rescue medications for two (2) or more days a week (for example, Short Acting Beta-2 Agonists)
   2. Nighttime symptoms occurring one or more times a week
   3. Minimum of two (2) exacerbations in the last 12 months requiring additional medical treatment (For example, systemic corticosteroids, emergency department visits, or hospitalization)
   4. Forced Expiratory Volume in less than one second (FEV1) is less than 80% predicted
   5. Symptoms greater than 2 days per week
   6. Limitation with normal activity
G. Dupixent will not be used with another monoclonal antibody

Additional Information:

Dupixent is NOT covered for members with the following criteria:
- Use not approved by the FDA; AND
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

Approval Duration:

Last Review: 1/2019
Last PARP Approval: 1/2019
Current PARP Approval: 3/2019
**Initial Approval:** 4 months

**Renewals:** 6 months

**Requires:**
- **Atopic Dermatitis:** Response to medication therapy (for example, reduction in lesions) or Investigator’s Global Assessment (IGA) of 0 or 1 clear’ or almost clear
- **Asthma of Eosinophilic Phenotype:**
  - Response to therapy (for example, by a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV1) from baseline, etc.)
  - Continued use of Dupixent as add on therapy to other asthma medications
- **Corticosteroid Dependent Asthma:**
  - Response to therapy (for example, by a decrease in dose of oral steroids from baseline, a decrease in exacerbations from baseline, improvement in Forced Expiratory Volume in less than one second (FEV1) from baseline, etc.)
  - Continued use of Dupixent as add on therapy to other asthma medications

**Dosing:**

**Asthma, moderate to severe**

- Initial: 400 mg (given as two 200 mg injections) or 600 mg (given as two 300 mg injections)
- Maintenance: 200 mg (following 400 mg initial dose) or 300 mg (following 600 mg initial dose) once every other week

**Asthma, oral corticosteroid dependent**

- Initial: 600 mg (given as two 300 mg injections)
- Maintenance: 300 mg once every other week

**Atopic dermatitis**

- Initial: 600 mg (given as two 300 mg injections)
- Maintenance: 300 mg once every other week

Last Review: 1/2019
Last PARP Approval: 1/2019
Current PARP Approval: 3/2019
**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

**References:**


