Clinical Policy: Dupilumab (Dupixent)

Reference Number: PA.CP.PHAR.336
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for Dupilumab (Dupixent®).

FDA Approved Indication(s)
Dupixent is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients 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.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that dupilumab (Dupixent) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Atopic Dermatitis (must meet all):

1. Diagnosis of atopic dermatitis;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. Failure of all of the following (a, b, and c) unless contraindicated or clinically significant adverse effects are experienced:
   a. Two formulary medium to very high potency topical corticosteroids, each trialed for ≥ 2 weeks;
   b. One non-steroidal topical therapy: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment and pimecrolimus 1% cream) or Eucrisa, each trialed for ≥ 4 weeks*;
      * *These agents may require prior authorization*
   c. One or more of the following systemic agents: corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
5. Dose does not exceed the following:
   a. Initial (one-time) dose: 600mg;
   b. Maintenance dose: 300mg every other week.

Approval duration: 16 weeks

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Atopic Dermatitis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or Continuity of Care policy applies;
2. Documentation of positive response to therapy (e.g. reduction in itching/scratching);

3. If request is for a dose increase, new dose does not exceed 300mg given every other week.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care policy applies;
   Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the IL-4Ra subunit shared by the IL-4 and IL-13 receptor complexes. Dupilumab inhibits IL-4 signaling via the Type I receptor and both IL-4 and IL-13 signaling through the Type II receptor.

Formulations:
Injection: 300 mg/2 mL solution in a single-dose pre-filled syringe with or without needle shield

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
References were reviewed and updated.	02/18	

References

1. Dupixent Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2017. Available at www.dupixent.com. Accessed November 15, 2017.
2. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. New England Journal of Medicine. 2016; 375: 2335-48.

3. Eichenfield F, Tom WL, Chamlin SL et al. Guidelines of Care for the Management of Atopic Dematitis. *J Am Acad Dermatol*. 2014 February; 70(2): 338–351.
4. Leshem YA, Hajar T, Hanifin JM, et al. What the Eczema Area and Severity Index score tells us about the severity of atopic dermatitis: an interpretability study. British Journal of Dermatology 2015; 172(5):1353-1357.