Dupixent® (dupilumab)
Effective 11/26/18

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by binding to the IL-4Rα subunit. Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, nitric oxide and IgE.

Coverage Guidelines

Approval will be granted if the member meets the following diagnosis specific criteria and documentation has been submitted.

Moderate-severe atopic dermatitis:

1. Member has a diagnosis of moderate-severe atopic dermatitis **AND**
2. Member is at least 18 years of age **AND**
3. Prescriber is an allergist/immunologist or dermatologist, or provides consultations notes from an allergist/immunologist or dermatologist.
4. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response or adverse reaction to ONE superpotent or potent topical corticosteroid †
    b. Contraindication to ALL superpotent or potent topical corticosteroids ‡

    AND
5. Member has had an inadequate response, adverse reaction or contraindication to topical tacrolimus

    AND
6. Prescriber has provided documentation of ONE of the following:
    - Inadequate response or adverse reaction to ONE systemic immunosuppressive therapy* (e.g.

azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid)
- Contraindication to ALL systemic immunosuppressive therapy

7. Dosing is appropriate (see Appendix A)

Add-on maintenance treatment of moderate to severe asthma with an eosinophilic phenotype:

1. Member is at least 12 years of age **AND**
2. Prescriber is an asthma specialist (i.e. allergist, immunologist, pulmonologist) **AND**
3. Member is symptomatic despite receiving one of the following:
    a. combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    b. combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as a separate inhaler; **or**
4. member requires chronic oral corticosteroids **AND**
5. evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO **AND**
6. Dosing is appropriate (see Appendix)

Oral corticosteroid dependent asthma:

1. Member is at least 12 years of age **AND**
2. Member requires chronic oral steroids for treatment of asthma **AND**
3. Dosing is appropriate (see Appendix)

**If member has tried systemic immunosuppressive therapy and trial with a superpotent or potent topical corticosteroid has not been documented, the trial may be bypassed*
† If member has tried lower potency corticosteroid, prescriber must provide clinical rationale for not utilizing superpotent/potent corticosteroid
‡ Trials with corticosteroids may be bypassed if the request clearly states that the treatment area is a sensitive area (facial/groin)

Continuation of Therapy

1. Reauthorizations for Atopic Dermatitis will be approved when documentation is submitted indicating a positive response to therapy.
2. Reauthorizations for Asthma will be approved when documentation is submitted indicating a positive response to therapy as evidenced by a decrease in oral steroid requirement and a decrease in asthma exacerbations.

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted as listed below based on diagnosis
    a. Atopic Dermatitis – 6 months
    b. Asthma – 12 months

Appendix

Dupixent® (dupilumab)	**Atopic dermatitis (moderate-severe):** 600 mg SQ followed by 300 mg every other week
	Moderate to severe eosinophilic asthma: 400mg or 600mg followed by 200mg or 300mg every other week.
	Oral corticosteroid dependent asthma: 600mg followed by 300mg every other week

References
N/A

Review History
06/2017: Reviewed P&T
10/01/2017: Implemented
03/01/2018: Reviewed and Revised (Adopted MH RS)
11/26/2018: Reviewed and Revised

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