SmartPA Criteria Proposal

Drug/Drug Class:	Respiratory Monoclonal Antibodies (RMA) PDL Edit
First Implementation Date:	July 11, 2019
Revised Date:	December 9, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state specific preferred drug list.

Why was this Issue Selected: Airway inflammation is key to asthma disease. Most asthmatic patients can manage their symptoms with a combination of inhaled corticosteroids (ICS) and long-acting beta agonists (LABAs). However, a small percentage of asthmatic patients have severe refractory asthma and yet are the greatest burden on the health care system (50% of asthma spend is on 5-10% of patients). Targeted therapies have been developed that yield better outcomes in specific patient types. These new therapies target key cells and mediators that drive inflammatory responses in the asthmatic lung. This new class of biologics for asthma target interleukin inhibition (IL-4, IL-5 and IL-13) to reduce eosinophils and periostin. Xolair is the exception as it targets elevated IgE in allergic asthma.

Total program savings for the PDL classes will be regularly reviewed.

Program-specific information:

Preferred Agents	Non-Preferred Agents
• Cinqair® • Fasenra® • Xolair®	• Dupixent® • Nucala®

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **Clinical Edit**

Data Sources:

☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug/Drug Class for review: Respiratory Monoclonal Antibodies
- Age Range: All appropriate MO HealthNet participants 6 years of age or older

Approval Criteria

- Prescribed by or in consultation with an appropriate specialist for the treated disease state **AND**
- Documented compliance on current therapy regimen **OR**
- For Cinqair:
  - Participant aged 18 years of age or older **AND**
  - Documented diagnosis of asthma with evidence of inadequate control **AND**
  - Documentation of eosinophilic phenotype
- For Fasenra:
  - Participant aged 12 years or older **AND**
  - Documented diagnosis of asthma with evidence of inadequate control **AND**
  - Documentation of eosinophilic phenotype
- For Xolair:
  - Documented diagnosis of asthma with evidence of inadequate control **AND**
    - Participant aged 6 years or older **AND**
    - Documented percutaneous skin test **OR**
    - Documented RAST allergy test **OR**
    - Documented in vitro reactivity to at least one perennial aeroallergen
  - Documented diagnosis of chronic idiopathic urticaria with evidence of inadequate control and participant aged 12 years or older **OR**
- For Dupixent:
  - Documented diagnosis of asthma with evidence of inadequate control:
    - Participant aged **6** years or older **AND**
    - Documented eosinophilic phenotype or dependence upon oral corticosteroids **AND**
    - Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents **OR**
    - Documented ADE/ADR to preferred agents
  - Documented diagnosis of moderate to severe atopic dermatitis:
    - Participant aged 6 years or older **AND**
    - Documentation of ≥ 1 of the following:
      - Involvement of at least 10% of body surface area (BSA)
      - Scoring Atopic Dermatitis (SCORAD) score of 20 or more
      - Investigator's Global Assessment (IGA) with a score ≥ 3
      - Eczema Area and Severity Index (EASI) score of ≥ 16
      - Incapacitation due to atopic dermatitis lesion location (e.g., head and neck, palms, soles, or genitalia) **AND**
    - Documented therapeutic trial or contraindication of:
      - 1 topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) **AND**
      - 1 topical calcineurin inhibitors (tacrolimus or pimecrolimus) **AND**
    - Inadequate response (or contraindication) to a 30 day minimum trial of at least 1 immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.) **AND**
    - Inadequate response to (or is not a candidate for) a 3 month minimum trial of phototherapy (e.g., psoralens with UVA light [PUVA], UVB, etc) provided participant has reasonable access to photo treatment **AND**
    - Participant not currently pregnant
    - **Renewal Criteria:**
      - Continue to meet above criteria **AND**
      - Documented response compared to baseline as measured by measures used to qualify moderate to severe AD at baseline (e.g., pruritus, BSA involvement, EASI, IGA, SCORAD)
- For Nucala:
  - Documented diagnosis of hypereosinophilic syndrome (HES) in the past 3 years and participant aged 12 years or older **OR**
  - And documented diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) in the past 3 years and participant aged 18 years or older **OR**

    - Documented diagnosis of asthma with evidence of inadequate control:
        - Participant aged 6 years or older **AND**
        - Documentation of eosinophilic phenotype **AND**
        - Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents **OR**
        - Documented ADE/ADR to preferred agents
- For documented diagnosis of chronic rhinosinusitis with nasal polyposis:
    - Claim is for Dupixent, **Nucala**, or Xolair **AND**
    - Participant aged 18 years or older **AND**
    - Participant not currently pregnant **AND**
    - Documented therapeutic trial with systemic corticosteroids or previous sino-nasal surgery **AND**
    - Documented previous and continuing concurrent therapy with an intranasal corticosteroid
- For all agents: inadequately controlled asthma defined by trial of inhaled corticosteroid in the last 45 days and 1 of the following:
    - Three short acting beta-2 agonist claims in the last 60 days
    - Short term oral steroid claim in the last 30 days
    - ED visit for treatment of asthma in the last 45 days

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List Edit)
Rule Type: PDL

Default Approval Period

1 year

References

1. “New England Journal of Medicine Publishes Two Positive Phase 3 Trials Showing Dupixent (Dupilumab) Improved Moderate-To-Severe Asthma”. Regeneron. May 21, 2018. Retrieved March 2019 from https://newsroom.regeneron.com/news-releases/news-release-details/new-england-journal-medicine-publishes-two-positive-phase-3
2. “Investigational-agents-for-asthma”. Retrieved March 2019 from https://www.uptodate.com
3. Evidence-Based Medicine Analysis: “Respiratory Monoclonal Antibodies – Therapeutic Class Review”, Conduent Business Services L.L.C., Richmond, VA; March 2021.
4. USPDI, Micromedex; 2021.
5. Drug Facts and Comparisons On-line; 2021.