SmartPA Criteria Proposal

Drug/Drug Class:	Respiratory Monoclonal Antibodies (RMA) PDL Edit
First Implementation Date:	July 11, 2019
Revised Date:	July 7, 2022
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**	☒ **Preferred Drug List**
☒ **Appropriate Indications**	☐ **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 documented diagnosis of moderate to severe asthma:**
  - ~~**Three short acting beta-2 agonist claims in the last 60 days OR**~~
  - **Compliance to 90 days of therapy with inhaled corticosteroid AND**
  - **Evidence of inadequate control defined as ≥ 2 exacerbations in the past year**
    - 2 claims of a short-term oral steroid in the past **6 months** ~~**30 days**~~ **OR**
    - **2** ED visits for treatment of asthma in the past **year** ~~**45 days**~~ **OR**
    - **Other documentation of moderate to severe asthma**
  - Claim is for Cinqair:
    - Participant aged 18 years of age or older **AND**
    - Documentation of eosinophilic phenotype
  - Claim is for Dupixent:
    - 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
  - Claim is for Fasenra:
    - Participant aged 12 years or older **AND**
    - Documentation of eosinophilic phenotype
  - Claim is for Nucala:
    - 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
  - Claim is for Xolair:
    - 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
- **For documented diagnosis of moderate to severe atopic dermatitis:**
  - Claim is for Dupixent:
    - 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 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 **AND**
    - **For Dupixent and Nucala: failure to achieve desired therapeutic outcomes with trial of Xolair**
- **For documented diagnosis of chronic idiopathic urticaria with evidence of inadequate control:**
    - Claim is for Xolair and participant aged ≥ 12 years or older
- **For documented diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) in past 3 years:**
    - Claim is for Nucala and participant is aged 18 years or older
- **For documented diagnosis of hypereosinophilic syndrome (HES) in past 3 years:**
    - Claim is for Nucala and participant is aged 12 years or older

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

- Evidence-Based Medicine Analysis: “Respiratory Monoclonal Antibodies – Therapeutic Class Review”, Conduent Business Services L.L.C., Richmond, VA; January 2022.
- USPDI, Micromedex; 2022.
- Drug Facts and Comparisons On-line; 2022.