SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Misc. Allergy and Asthma Related Monoclonal Antibodies PDL Edit *(formerly the Respiratory Monoclonal Antibodies (RMA) PDL Edit)*
First Implementation Date:	July 11, 2019
Proposed Date:	September 15, 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 Issue Selected: The targeted immune modulators in this class are a diverse group of agents with a range of indications focusing on immune response modulation. The agents vary in both their molecular targets and mechanisms of action, with different agents achieving an immunosuppressive goal via different biological pathways. Indications for agents in this class include a variety of allergy and asthma related conditions including moderate to severe asthma, moderate to severe atopic dermatitis, chronic rhinosinusitis with nasal polyposis, chronic idiopathic urticaria, eosinophilic granulomatosis with polyangiitis (EGPA), hypereosinophilic syndrome (HES), and eosinophilic esophagitis.

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

Program-specific information:

Preferred Agents	Non-Preferred Agents
• Adbry™ • Cinqair® • Fasenra® • Xolair®	• Dupixent® • Nucala® • Tezspire™

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: Targeted Immune Modulators, Misc. Allergy and Asthma Related Monoclonal Antibodies
- Age Range: All appropriate MO HealthNet participants 6 years of age or older

Approval Criteria

- ~~Documented compliance on current therapy regimen OR~~
- **For documented diagnosis of moderate to severe asthma (Cinqair, Dupixent, Fasenra, Nucala, Tezspire, and Xolair):**
  - **Prescribed by or in consultation with a pulmonologist, allergist, or immunologist AND**
  - Participant is of an indicated age for the product requested:
    - Cinqair: aged 18 years of age or older
    - Fasenra **and Tezspire**: aged 12 years or older
    - Dupixent, Nucala, and Xolair: aged 6 years or older **AND**
  - **Participant must have experienced at least one exacerbation in the last 12 months despite continued compliant use of a high dose inhaled corticosteroid in combination with either a LABA or LAMA as evidenced by paid claims**
    - **Exacerbations for asthma are defined as:**
      - **One oral corticosteroid burst (for asthma)**
      - **ER Visit (for asthma)**
      - **Hospitalization (for asthma)**
      - **Office visit for asthma worsening or emergency, not routine asthma follow-up AND**
  - **Prescriber attestation of moderate to severe asthma with at least one of the following:**
    - **Eosinophilic asthma, defined as EOS ≥ 300 cells/µl**
    - **Oral corticosteroid dependent asthma AND EOS ≥ 150 cells/µl**
    - **Xolair only: Documented percutaneous skin test, RAST allergy test, or in vitro reactivity to at least one perennial aeroallergen**
    - **Tezspire only: confirmed non-eosinophilic asthma AND 2 asthma exacerbations in the last 12 months despite compliance on maintenance asthma therapy**
    - **Dupixent only: oral corticosteroid dependent asthma AND confirmed non-eosinophilic asthma**
  - Requests for non-preferred agents: Participants must have documented failure to achieve desired therapeutic outcomes with trial on at least 2 preferred agents if indicated:
    - Documented trial period of preferred agents (6 months of therapy) **OR**
    - Documented ADE/ADR to preferred agents **AND**
  - Initial approval of prior authorization is 12 months.
  - **Renewal of prior authorization may be given for up to 12 months following prescriber attestation of documented response to treatment compared to baseline based on one of the following:**
    - **Decreased use of rescue inhalers**
    - **Decreased exacerbations**
- **For documented diagnosis of moderate to severe atopic dermatitis (Adbry and Dupixent):**
  - **Prescribed by or in consultation with an immunologist, allergist, or dermatologist AND**
  - **Failure to achieve desired therapeutic outcome with trial of at least any two of the following classes of therapy for 60 days each:**
    - **Topical corticosteroid**
    - **Topical calcineurin inhibitor**
    - **Phototherapy**
    - **Phosphodiesterase-4 (PDE-4) inhibitor**
    - **Oral corticosteroid for the treatment of atopic dermatitis**
    - **Oral immunosuppressant for the treatment of atopic dermatitis**
    - **Topical or oral Janus Kinase (JAK) inhibitor**
  - Requests for non-preferred agents: Participants must have documented failure to achieve desired therapeutic outcomes with trial on at least 1 preferred agent if indicated **(participants 6 months to 17 years old may access Dupixent without a trial of Adbry)**:
    - Documented trial period of preferred agents (6 months of therapy) **OR**
    - Documented ADE/ADR to preferred agents **AND**
  - Initial approval of prior authorization is 12 months.

- Renewal of prior authorization may be given for up to 12 months following prescriber attestation of documented response to treatment compared to baseline

- **For documented diagnosis of chronic rhinosinusitis with nasal polyposis (Dupixent, Nucala, and Xolair):**
  - **Prescribed by or in consultation with an allergist, pulmonologist, or otolaryngologist AND**
  - Participant aged 18 years or older **AND**
  - **Physician attests the individual meets all of the following criteria:**
    - **Confirmed diagnosis of chronic rhinosinusitis with nasal polyposis AND**
    - **Chronic rhinosinusitis with nasal polyposis is inadequately controlled by at least two of the following:**
      - **Intranasal steroids for at least 90 days**
      - **Systemic corticosteroid therapy for at least 45 days**
      - **One or more prior nasal surgeries while on an intranasal steroid to prevent recurrence**
  - Requests for non-preferred agents: Participants must have documented failure to achieve desired therapeutic outcomes with trial on at least 1 preferred agent if indicated:
    - Documented trial period of preferred agents (6 months of therapy) **OR**
    - Documented ADE/ADR to preferred agents **AND**
  - Initial approval of prior authorization is 12 months.
  - Renewal of prior authorization may be given for up to 12 months following prescriber attestation of documented response to treatment compared to baseline
- **For documented diagnosis of chronic idiopathic urticaria with evidence of inadequate control (Xolair):**
  - Participant aged 12 years or older
- **For documented diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (Nucala):**
  - Participant aged 18 years or older
- **For documented diagnosis of hypereosinophilic syndrome (HES) (Nucala):**
  - Participant aged 12 years or older
- **For documented diagnosis of eosinophilic esophagitis (Dupixent):**
  - **Prescribed by or in consultation with a gastroenterologist, immunologist, or allergist AND**
  - **Participant aged 12 years or older AND**
  - **Diagnosis of eosinophilic esophagitis by endoscopic esophageal biopsy showing the presence of eosinophils (e.g., ≥ 15 eosinophils per high-powered field) AND**
  - **Signs and current symptoms of esophageal dysfunction present AND**
  - **Inadequate response, intolerable adverse effects, or contraindications to all of the following treatments:**
    - **High-dose proton pump inhibitor for at least 8 weeks**
    - **Swallowed topical corticosteroid (e.g., fluticasone, oral budesonide)**
    - **Dietary therapy (i.e., avoidance of food allergen triggers)**
  - **Initial approval of prior authorization is 12 months.**
  - **Renewal of prior authorization may be given for up to 12 months following prescriber attestation of documented response to treatment compared to baseline.**

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.
- Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; July 2022.
- Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; February 2020.
- Dupixent [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; June 2022.
- Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; February 2021.
- Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline LLC; January 2022.
- Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2021.
- Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; July 2021.
- USPDI, Micromedex; 2022.
- Drug Facts and Comparisons On-line; 2022.