SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Misc. Allergy and Asthma Related Monoclonal Antibodies PDL Edit
First Implementation Date:	July 11, 2019
Proposed Date:	July 18, 2023
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), eosinophilic esophagitis, and prurigo nodularis.

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 & Asthma Related Monoclonal Antibodies
- Age Range: All appropriate MO HealthNet participants 6 years of age or older

Approval Criteria

- **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 **(EOS ≥ 150 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 refractory to therapy with at least two of the following:
      - Intranasal steroids for at least 90 days
      - Systemic corticosteroid therapy burst for nasal polyps
      - 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.
- **For documented diagnosis of prurigo nodularis (Dupixent):**
  - **Prescribed by or in consultation with a dermatologist AND**
  - **Participant aged 18 years or older AND**
  - **Physician attests the individual meets all of the following criteria:**
    - **Documentation of ≥ 20 nodular lesions AND**
    - **Documentation of severe or very severe itch defined as Worst-Itch Numeric Rating Scale (WI-NRS score ≥ 7) AND**
    - **Inadequate response, intolerable adverse effects, or contraindications to at least 1 month of therapy with medium to super-high potency topical corticosteroid**
  - **Initial approval of prior authorization is 6 months**
  - **Renewal of prior authorization may be given for up to 12 months following prescriber attestation of documented response to treatment compared to baseline by ≥ 4 point reduction in WI-NRS from baseline.**

- Documentation of appropriate diagnosis and participant age range for requested agent:

Biologic Agent	Brand	Indication *(aged ≥ 18 years unless otherwise indicated)*
benralizumab	Fasenra®	• Severe asthma with an eosinophilic phenotype (aged ≥ 12 years)
dupilumab	Dupixent®	• Atopic dermatitis (aged ≥ 6 months) • Chronic rhinosinusitis with nasal polyposis (CRSwNP) • Eosinophilic esophagitis (EoE) • Moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma (aged ≥ 6 years) • **Prurigo nodularis (PN)**
mepolizumab	Nucala®	• Chronic rhinosinusitits with nasal polyps (CRSwNP) • Eosinophilic granulomatosis with polyangiitis (EGPA) • Hypereosinophilic syndrome (HES) (aged ≥ 12 years) • Severe asthma with an eosinophilic phenotype (aged ≥ 6 years)
omalizumab	Xolair®	• Chronic rhinosinusitis with nasal polyps (CRSwNP) • Chronic spontaneous urticaria (CSU) (aged ≥ 12 years) • Moderate to severe persistent asthma with a positive skin test or in vitro reactivity to a perennial aeroallergen (aged ≥ 6 years)
reslizumab	Cinqair®	• Severe asthma with an eosinophilic phenotype
tezepelumab-ekko	Tezspire™	• Severe asthma (aged ≥ 12 years)
tralokinumab-ldrm	Adbry™	• Atopic dermatitis

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 and Fiscal Analysis: “Therapeutic Class Review: IMMUNOLOGIC AGENTS: Targeted Immune Modulators; Miscellaneous Allergy and Asthma-Related Antibodies”, Gainwell Technologies; Last updated April 20, 2023.
- Evidence-Based Medicine Analysis: “Target Immune Modulators: Allergy and Asthma Related Antibodies”, UMKC-DIC; March 2023.
- Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; December 2021.

- Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; January 2019.
- Dupixent [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; October 2022.
- Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; October 2019.
- Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline LLC; March 2023.
- Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.
- Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.