SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Interleukin-6 (IL-6) Receptor Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
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: Actemra® (tocilizumab) and Kevzara® (sarilumab), are interleukin-6 (IL-6) receptor antagonists which inhibit endogenous IL-6 thereby initiating a variety of immunological responses. Inhibition of IL-6 decreases cytokine and acute phase reactant production. For adults, Actemra is indicated for the treatment of moderately to severely active rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs), giant cell arthritis, and slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease. For participants aged 2 years or older, Actemra is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS), active polyarticular juvenile idiopathic arthritis, and active systemic juvenile idiopathic arthritis. Kevzara is indicated for the treatment of moderately to severely active rheumatoid arthritis in adults who have had an inadequate response or intolerance to one or more DMARDs.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Actemra® Syringe	• Actemra® ACTPen®/Vial • Kevzara®

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 class for review: Targeted Immune Modulators, Interleukin-6 (IL-6) Receptor Inhibitors
- Age range: All appropriate MO HealthNet participants aged 18 years or older unless indicated otherwise

Approval Criteria

- Documented compliance on current therapy **OR**
- Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitor (trial defined as duration of therapy with class not agent) **AND**
- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agents (6 months of therapy) **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Actemra ACTPen and Vial: Clinical Consultant Review for medical necessity **AND**
- ~~**Documented diagnosis of rheumatoid arthritis:**~~
  - ~~**Adequate therapeutic trial of methotrexate OR**~~
  - ~~**Contraindication to methotrexate therapy OR**~~
- Documentation of appropriate diagnosis and participant age range for requested agent:

Generic	Brand	Indication
Sarilumab	Kevzara®	• Rheumatoid arthritis
Toclizumab	Actemra® Actemra® ACTPen®	• Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (aged 2 or older)* • Giant cell arteritis* • Polyarticular juvenile idiopathic arthritis (aged 2 or older) • Rheumatoid arthritis • **Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)*** • Systemic juvenile idiopathic arthritis (aged 2 or older)

**Approvable as first-line therapy without trial of TNF inhibitors*

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:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Targeted Immune Modulators (Biologics – DMARDS [IL-6, TNF, IL-17A Antibody/IL-17 RA & IL-23/IL-12, JAK Inhibitors, CAPs agents, Select/Other Agents])". UMKC-DIC; August 2022.

- Evidence-Based Medicine and Fiscal Analysis: “Targeted Immune Modulators: Selected/Miscellaneous Agents– Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783
- Actemra [package insert]. South San Francisco, CA: Genentech Inc; June 2022.
- Kevzara [package insert]. Bridgewater, NJ: Sanofi Biotechnology; April 2018.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.