SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Interleukin-6 (IL-6) Receptor Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
Revised Date:	October 5, 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: 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. Actemra is FDA approved to treat moderate to severe rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis (pJIA and sJIA), giant cell arteritis (GCA or temporal arteritis), systemic sclerosis-associated interstitial lung disease (SSc-ILD), cytokine release syndrome (CRS), and coronavirus disease 2019 (COVID-19). Kevzara is indicated for the treatment of adults with moderate to severe RA who have had an inadequate response or intolerance to 1 or more disease-modifying antirheumatic drugs (DMARDs) and to treat adults with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

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**
☒ **Preferred Drug List**
☐ **Appropriate Indications**
☐ **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**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Biologic Agent	Brand	Indication
sarilumab	Kevzara®	• **Polymyalgia rheumatica (PMR)*** • Rheumatoid arthritis
toclizumab	Actemra® Actemra® ACTPen®	• Coronavirus disease 2019 (COVID-19)** • Cytokine release syndrome (aged 2 or older)* • Giant cell arteritis* • Polyarticular juvenile idiopathic arthritis (aged 2 or older) • Rheumatoid arthritis • 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.*
*** When Actemra is used for this indication it is not a separately payable service from the inpatient per diem and a prior authorization will not be issued.*

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 and Fiscal Analysis: “IMMUNOLOGIC AGENTS: Targeted Immune Modulators, IL-6 Receptor Inhibitors”, Gainwell Technologies; Last updated April 11, 2023.

- 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; March 2023.
- Actemra [package insert]. South San Francisco, CA: Genentech Inc; December 2022.
- Kevzara [package insert]. Bridgewater, NJ: Sanofi Biotechnology; February 2023.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.