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:	June 18, 2020
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) is an interleukin-6 (IL-6) receptor antagonist which inhibits endogenous IL-6 which initiates a variety of immunological responses. Inhibition of IL-6 decreases cytokine and acute phase reactant production. This agent is indicated for the treatment of moderately to severely active rheumatoid arthritis (RA) in adults who have tried one or more disease-modifying anti-rheumatic drugs (DMARDs) and had an inadequate response, giant cell arthritis, severe or life-threatening cytokine release syndrome (CRS), and polyarticular juvenile idiopathic arthritis (PJIA) in those 2 years of age or older. Kevzara® (sarilumab), another IL-6 receptor antagonist, 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. Both agents are currently under investigation for the treatment of COVID-19 associated pulmonary complications with elevated IL-6 levels. These agents can lower the ability of the immune system to fight infections, so tuberculosis testing is recommended prior to initiating therapy. It is recommended to not initiate these agents if a participant has an absolute neutrophil count (ANC) is below 2000 per mm^3 and/or if an ALT or AST greater than 1.5 times the upper limit of normal (ULN). It is also recommended to not initiate tocilizumab if a participant has a platelet count below 100,000 per mm^3 and to not initiate sarilumab if a participant has a platelet count below 150,000 per mm^3. Avoid administration of live vaccines when using these agents. Do not administer during an active infection and use caution in those who may be at an increased risk for developing gastrointestinal perforations.

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 greater unless indicated otherwise

Approval Criteria

- **Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitors defined as:**
  - **Combination therapy of 2 TNF inhibitors OR**
  - **Monotherapy of 1 TNF inhibitor AND**
- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agents **(6 months of therapy)**
  - 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 in the past 720 days **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®	• Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (aged 2 or older; approvable as first-line therapy without trial of TNF inhibitors) • Giant cell arteritis (approvable as first-line therapy without trial of TNF inhibitors) • Polyarticular juvenile idiopathic arthritis (aged 2 or older) • Rheumatoid arthritis • Systemic juvenile idiopathic arthritis (aged 2 or older)

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are 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

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783
5. Evidence-Based Medicine Analysis: "Targeted Immune Modulators (Biologics – DMARDS)". UMKC-DIC; April 2020.
6. Evidence-Based Medicine and Fiscal Analysis: "Targeted Immune Modulators: IL-6 Inhibitors – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; April 2020.
7. Actemra [package insert]. South San Francisco, CA: Genentech Inc; 2020.
8. Kevzara [package insert]. Bridgewater, NJ: Sanofi Biotechnology; 2018.