SmartPA Criteria Proposal

<table>
<thead>
<tr>
<th>Drug/Drug Class:</th>
<th>Targeted Immune Modulators, Interleukin-6 (IL-6) Receptor Inhibitors PDL Edit</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Implementation Date:</td>
<td>January 22, 2004</td>
</tr>
<tr>
<td>Revised Date:</td>
<td>October 1, 2020</td>
</tr>
<tr>
<td>Prepared For:</td>
<td>MO HealthNet</td>
</tr>
<tr>
<td>Prepared By:</td>
<td>MO HealthNet/Conduent</td>
</tr>
<tr>
<td>Criteria Status:</td>
<td>☐ Existing Criteria, ☑ Revision of Existing Criteria, ☐ New Criteria</td>
</tr>
</tbody>
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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) below 2000 per mm³ 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 mm³ and to not initiate sarilumab if a participant has a platelet count below 150,000 per mm³. 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.

<table>
<thead>
<tr>
<th>Program-Specific Information:</th>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Criteria:</td>
<td>☐ Increased risk of ADE</td>
<td>☑ Preferred Drug List</td>
</tr>
<tr>
<td>Data Sources:</td>
<td>☐ Only Administrative Databases</td>
<td>☑ Databases + Prescriber-Supplied</td>
</tr>
</tbody>
</table>

SmartPA PDL Proposal Form
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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

- **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 OR
  - Contraindication to methotrexate therapy OR
- Documentation of appropriate diagnosis and participant age range for requested agent:

<table>
<thead>
<tr>
<th>Sarilumab</th>
<th>Kevzara®</th>
<th>Rheumatoid arthritis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocilizumab</td>
<td>Actemra®</td>
<td>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)</td>
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<tr>
<td></td>
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<td>Giant cell arteritis (approvable as first-line therapy without trial of TNF inhibitors)</td>
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<td></td>
<td></td>
<td>Polyarticular juvenile idiopathic arthritis (aged 2 or older)</td>
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<tr>
<td></td>
<td></td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Systemic juvenile idiopathic arthritis (aged 2 or older)</td>
</tr>
</tbody>
</table>

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

2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.