Drug/Drug Class: Targeted Immune Modulators, Tumor Necrosis Factor (TNF) Inhibitors PDL Edit

First Implementation Date: January 22, 2004

Revised Date: October 1, 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: Tumor necrosis factor (TNF) inhibitors are agents that bind to the TNF alpha receptor and interfere with cytokine binding. The interference of TNF inhibits the cytokine driven inflammatory response and helps alleviate the symptoms of several auto-immune disorders, including rheumatoid arthritis, psoriasis, and ankylosing spondylitis. Although these agents interact with the same biological target and pathway, the structure and mechanism of action of these agents vary. TNF inhibitors have demonstrated equal efficacy to methotrexate (MTX) in treating rheumatoid arthritis and when TNF inhibitors and MTX are used in combination a greater level of efficacy is achieved than either achieves alone. There are currently 5 agents in this class, and while there is a great deal of overlap in their indications, there are also unique indications for each. Each agent is administered through either the subcutaneous route, intravenous route, or either route depending on the indication. These agents display a wide range of potentially serious adverse effects, including infusion reactions, neutropenia, infection, heart failure, malignancy, and the development of autoantibodies against the agent leading to decreased efficacy over time. The TNF inhibitors are commonly reserved for participants with moderate-to-severe disease after failure to control disease progression first line therapies.

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></td>
<td>• Enbrel®</td>
<td>• Avsola™</td>
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<tr>
<td></td>
<td>• Humira®</td>
<td>• Cimzia®</td>
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<td>• Inflectra®</td>
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<td></td>
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<td>• Remicade®</td>
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<td></td>
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<td>• Renflexis®</td>
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<td></td>
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<td>• Simponi®</td>
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<td>• Simponi ARIA®</td>
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</tbody>
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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, Tumor Necrosis Factor (TNF) Inhibitors
- Age range: All appropriate MO HealthNet participants aged 18 years or older unless indicated otherwise

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 preferred agents
  - Documented trial period of preferred agents OR
  - Documented ADE/ADR to preferred agents 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>Generic</th>
<th>Brand</th>
<th>Indication</th>
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</table>
| Adalimumab    | Humira®       | • Ankylosing spondylitis  
                  • Crohn's disease (aged 6 or older)  
                  • Hidradenitis suppurativa (aged 12 or older)  
                  • Plaque psoriasis  
                  • Polyarticular juvenile idiopathic arthritis (aged 2 or older)  
                  • Psoriatic arthritis  
                  • Rheumatoid arthritis  
                  • Ulcerative colitis  
                  • Uveitis (aged 2 or older) |
| Certolizumab Pegol | Cimzia®       | • Ankylosing spondylitis  
                  • Crohn's disease  
                  • Non-radiographic axial spondyloarthritis  
                  • Plaque psoriasis  
                  • Psoriatic arthritis  
                  • Rheumatoid arthritis |
| Entanercept   | Enbrel®       | • Ankylosing spondylitis  
                  • Plaque psoriasis (aged 4 or older)  
                  • Polyarticular juvenile idiopathic arthritis (aged 2 or older)  
                  • Psoriatic arthritis  
                  • Rheumatoid arthritis |
| Golimumab     | Simponi® Simponi ARIA® | • Ankylosing spondylitis  
                  • Psoriatic arthritis  
                  • Rheumatoid arthritis  
                  • Ulcerative colitis |
### Denial Criteria

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

### Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>Other:</th>
</tr>
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</table>

### Disposition of Edit

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

### Default Approval Period

1 year
14. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.