### Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** The targeted immune modulators select agents are a diverse group of agents with a range of indications focusing on immune response modulation. The agents vary in both their molecular targets and mechanisms of action, with each agent achieving its immunosuppressive goal via different biological pathways. Benlysta® (belimumab) is a monoclonal antibody that inhibits the survival of B cell lymphocytes, thus decreasing antibody output and diminishing the autoimmune response. It is only indicated for systemic lupus erythematosus (SLE) in participants ≥ 5 years of age. Otezla® (apremilast) is a phosphodiesterase-4 enzyme inhibitor indicated for psoriatic arthritis, plaque psoriasis, and oral ulcers of Behcet’s disease. It has the unique distinction of being the only oral member of this class. Orencia® (abatacept) is a selective T-Cell costimulation blocker indicated for rheumatoid arthritis, juvenile idiopathic arthritis in children ≥ 6 years old, and psoriatic arthritis. Entyvio® (vedolizumab) is a selective adhesion-molecule inhibitor monoclonal antibody indicated for ulcerative colitis and Crohn’s disease.

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

### Program-Specific Information:

<table>
<thead>
<tr>
<th>Program-Specific Information</th>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Criteria:</strong></td>
<td>□ Increased risk of ADE</td>
<td>☒ Preferred Drug List</td>
</tr>
<tr>
<td></td>
<td>□ Appropriate Indications</td>
<td>□ Clinical Edit</td>
</tr>
<tr>
<td><strong>Data Sources:</strong></td>
<td>□ Only Administrative Databases</td>
<td>☒ Databases + Prescriber-Supplied</td>
</tr>
</tbody>
</table>

**Drug/Drug Class:** Targeted Immune Modulators, Select Agents 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
Setting & Population

- Drug class for review: Targeted Immune Modulators, Select Agents
- 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:
  o Combination therapy of 2 TNF inhibitors OR
  o Monotherapy of 1 TNF inhibitor AND
- For Otezla: approved as first-line therapy with documented diagnosis of oral ulcers associated with Behcet's disease:
  o Adequate therapeutic trial of triamcinolone, tetracyclines or colchicine in the past 30 days
- Documented diagnosis of rheumatoid arthritis:
  o Adequate therapeutic trial of methotrexate OR
  o Contraindication to methotrexate therapy OR
- Documentation of appropriate diagnosis and participant age range for requested agent:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand</th>
<th>Indications</th>
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</thead>
</table>
| Abatacept  | Orencia® | • Polyarticular Juvenile idiopathic arthritis (aged 2 or older) 
|            |       | • Psoriatic arthritis                                                       |
|            |       | • Rheumatoid arthritis                                                      |
| Apremilast | Oteza® | • Oral ulcers of Behcet’s Disease                                           |
|            |       | • Plaque psoriasis                                                          |
|            |       | • Psoriatic arthritis                                                      |
| Belimumab  | Benlysta® | • Systemic lupus erythematosus (approvable for first-line therapy without trial of TNF inhibitors) |
| Vedolizumab| Entyvio® | • Crohn’s disease                                                           |
|            |       | • Ulcerative colitis                                                       |

Denial Criteria

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

Required Documentation

- Laboratory Results:
- MedWatch Form: [ ]
- Progress Notes: [ ]
- Other: [ ]

Disposition of Edit

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

Default Approval Period

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