Drug/Drug Class: Targeted Immune Modulators, Select Agents PDL Edit
First Implementation Date: January 22, 2004
Revised Date: October 14, 2021
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: 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>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Otezla®</td>
<td>• Benlysta®</td>
</tr>
<tr>
<td></td>
<td>• Entyvio®</td>
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<tr>
<td></td>
<td>• Orencia®</td>
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<td>• Orencia® ClickJect™</td>
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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, Select Agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older unless otherwise indicated
Approval Criteria

- Documented compliance on current therapy OR
- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agent OR
  - Documented ADE/ADR to preferred agent AND
- 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
- For Entyvio for ulcerative colitis: adequate therapeutic 6 month trial of Xeljanz
- For Otezla: documented diagnosis of oral ulcers associated with Behcet’s disease:
  - Adequate therapeutic trial of triamcinolone, tetracyclines or colchicine in past 30 days
- For documented diagnosis of rheumatoid arthritis:
  - Adequate therapeutic trial of methotrexate OR
  - Contraindication to methotrexate therapy AND
- 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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</thead>
<tbody>
<tr>
<td>Abatacept</td>
<td>Orencia®</td>
<td>• Polyarticular juvenile idiopathic arthritis (aged 2 or older)</td>
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<tr>
<td></td>
<td>Orencia® ClickJect™</td>
<td>• Psoriatic arthritis</td>
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<tr>
<td></td>
<td></td>
<td>• Rheumatoid arthritis</td>
</tr>
<tr>
<td>Apremilast</td>
<td>Otezla®</td>
<td>• Oral ulcers of Behcet’s disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Plaque psoriasis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Psoriatic arthritis</td>
</tr>
<tr>
<td>Belimumab</td>
<td>Benlysta®</td>
<td>• Systemic lupus erythematosus (approveable for first-line therapy without trial of TNF inhibitors) (aged 5 or older)</td>
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<tr>
<td></td>
<td></td>
<td>• Lupus nephritis</td>
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<tr>
<td>Vedolizumab</td>
<td>Entyvio®</td>
<td>• Crohn’s disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ulcerative colitis</td>
</tr>
</tbody>
</table>

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

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
8. Evidence-Based Medicine Analysis: “Targeted Immune Modulators (Biologics – DMARDS)”.
   UMKC-DIC; April 2021.
9. Evidence-Based Medicine and Fiscal Analysis: “Targeted Immune Modulators:
   Selected/Miscellaneous Agents– Therapeutic Class Review”, Conduent Business Services, L.L.C.,
   Richmond, VA; June 2021.