

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Targeted Immune Modulators, Select Agents PDL Edit
<b>First Implementation Date:</b>	January 22, 2004
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Otezla®</li> </ul>	<ul style="list-style-type: none"> <li>Benlysta®</li> <li>Entyvio®</li> <li>Orencia®</li> <li>Orencia® ClickJect™</li> </ul>

**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, Select Agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older unless otherwise indicated

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## 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: adequate therapeutic 6 month trial of Simponi or Xeljanz **AND**
- For Otezla: approved as first-line therapy with documented diagnosis of oral ulcers associated with Behcet's disease:
  - Adequate therapeutic trial of triamcinolone, tetracyclines or colchicine in past 30 days **AND**
- 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:

Generic	Brand	Indication
Abatacept	Orencia® Orencia® ClickJect™	<ul style="list-style-type: none"> <li>• Polyarticular juvenile idiopathic arthritis (aged 2 or older)</li> <li>• Psoriatic arthritis</li> <li>• Rheumatoid arthritis</li> </ul>
Apremilast	Otezla®	<ul style="list-style-type: none"> <li>• Oral ulcers of Behcet's disease</li> <li>• Plaque psoriasis</li> <li>• Psoriatic arthritis</li> </ul>
Belimumab	Benlysta®	<ul style="list-style-type: none"> <li>• Systemic lupus erythematosus (approvable for first-line therapy without trial of TNF inhibitors) (aged 5 or older)</li> <li>• <b>Lupus nephritis</b></li> </ul>
Vedolizumab	Entyvio®	<ul style="list-style-type: none"> <li>• Crohn's disease</li> <li>• Ulcerative colitis</li> </ul>

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents

## 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

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## References

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2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc; June 2020.
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5. Benlysta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.
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7. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783.
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.

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