

SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Select Agents PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<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"> • Benlysta® • Entyvio® • Orencia® • Orencia® ClickJect™ • Otezla®

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 greater 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**
- **For Orencia: 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 the past 30 days
- Documented diagnosis of rheumatoid arthritis:
 - Adequate therapeutic trial of methotrexate in the past 720 days **OR**
 - Contraindication to methotrexate therapy **OR**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Generic	Brand	Indication
Abatacept	Orencia®	<ul style="list-style-type: none"> • Polyarticular Juvenile idiopathic arthritis (aged 2 or older) • Psoriatic arthritis • Rheumatoid arthritis
Apremilast	Otezla®	<ul style="list-style-type: none"> • Oral ulcers of Behcet's Disease • Plaque psoriasis • Psoriatic arthritis
Belimumab	Benlysta®	<ul style="list-style-type: none"> • Systemic lupus erythematosus (approvable for first-line therapy without trial of TNF inhibitors)
Vedolizumab	Entyvio®	<ul style="list-style-type: none"> • 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:

Progress Notes:

MedWatch Form:

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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