

SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Select Agents PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	September 15, 2022
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 indicated for the treatment of active, autoantibody-positive systemic lupus erythematosus (SLE) in addition to the treatment of active lupus nephritis. 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, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and prophylaxis of active graft versus host disease. Entyvio® (vedolizumab) is a selective adhesion-molecule inhibitor monoclonal antibody indicated for ulcerative colitis and Crohn’s disease. The most recent FDA-approved agent in the class is Saphnelo™ (anifrolumab-fnia) which is indicated for the treatment of SLE, but unlike Benlysta which is approved down to age 5, Saphnelo is currently only approved for use in adults.

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"> Otezla® 	<ul style="list-style-type: none"> Benlysta® Entyvio® Orencia® Orencia® ClickJect™ Saphnelo™

- 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

Approval Criteria

- Documented compliance on current therapy **OR**
- For treatment of Crohn's disease, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis:
 - Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitor (trial defined as duration of therapy with class not agent) **AND**
 - For Entyvio for ulcerative colitis: adequate therapeutic 6 month trial of Xeljanz **OR**
 - For requests for non-preferred agents for plaque psoriasis or psoriatic arthritis:
 - 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
- For Otezla for oral ulcers associated with Behcet's disease: adequate therapeutic trial of triamcinolone, tetracyclines or colchicine in past 30 days
- **For Orencia for acute graft-versus-host disease: Clinical consultant review required**
- ~~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"> • Polyarticular juvenile idiopathic arthritis (aged 2 or older) • Acute graft-versus-host disease prophylaxis (aged 2 or older) • Psoriatic arthritis • Rheumatoid arthritis
Anifrolumab-fnia	Saphnelo™	<ul style="list-style-type: none"> • Systemic lupus erythematosus (approvable for first-line therapy without trial of TNF inhibitors)
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) (aged 5 or older) • Lupus nephritis (aged 5 or older)
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 all approval criteria are not met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

SmartPA PDL Proposal Form

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Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Targeted Immune Modulators (Biologics – DMARDS [IL-6, TNF, IL-17A Antibody/IL-17 RA & IL-23/IL-12, JAK Inhibitors, CAPs agents, Select/Other Agents])". UMKC-DIC; August 2022.
- 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.
- Benlysta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; July 2022.
- Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals America Inc; June 2022.
- Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; December 2021.
- Otezla [package insert]. Thousand Oaks, CA: Amgen Inc; December 2021.
- Saphnelo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.
- 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Singh et al. Arthritis Care & Research – DOI 10.1002/acr.22783.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.