SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Select Agents PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	July 18, 2023
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 in this class have indications for disease states such as systemic lupus erythematosus, lupus nephritis, ulcerative colitis, Crohn's disease, rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and plaque psoriasis. The agents vary in both their molecular targets and mechanisms of action, with each agent achieving its immunosuppressive goal via different biological pathways. Agents in this class have mechanisms of action that are unique to other Targeted Immune Modulator PDL classes.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Otezla®	• Benlysta® • Entyvio® • Orencia® • Orencia® ClickJect™ • Saphnelo™ • **Sotyktu™** • **Spevigo®**

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, plaque psoriasis, 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 Spevigo for generalized pustular psoriasis flares:**
  - **Diagnosis confirmed by:**
    - **Documented Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) AND**
    - **Presence of fresh pustules (new appearance or worsening of pustules) AND**
    - **At least 5% of body surface area covered with erythema and the presence of pustules AND**
  - **Adequate therapeutic 6 month trial of tumor necrosis factor (TNF) inhibitor (trial defined as duration of therapy with class not agent)**
  - **Approval is for 1 month only.**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Biologic Agent	Brand	Indication
abatacept	Orencia® Orencia® ClickJect™	• 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™	• Systemic lupus erythematosus*
apremilast	Otezla®	• Oral ulcers of Behcet's disease* • Plaque psoriasis • Psoriatic arthritis
belimumab	Benlysta®	• Systemic lupus erythematosus (aged 5 or older)* • Lupus nephritis (aged 5 or older)*
deucravacitinib	**Sotyktu™**	• **Plaque psoriasis**
spesolimab-sbzo	**Spevigo®**	• **Generalized pustular psoriasis flares**
vedolizumab	Entyvio®	• Crohn's disease • Ulcerative colitis

**Approvable as first-line therapy without trial of TNF inhibitors*

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

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: IMMUNOLOGIC AGENTS: Targeted Immune Modulators, Select Agents”, Gainwell Technologies; Last updated April 6, 2023.
- 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; March 2023.
- Benlysta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; February 2023.
- 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.
- Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.
- Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.