SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Interleukin (IL)-17A Antibody/IL-17 Receptor Antagonists PDL Edit
First Implementation Date:	TBD
Proposed Date:	June 17, 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: Interleukins (ILs) are pro-inflammatory cytokines that stimulate the recruitment and proliferation of other immune cells, leading to an increase in inflammation at the site of activity. The IL-17 pathway plays a major role in several auto-immune disorders, including psoriasis, psoriatic arthritis, and spondyloarthritis. Taltz® and Cosentyx® selectively bind to interleukin 17A (IL-17A) and inhibit its interaction with the IL-17 receptor while Siliq® binds to the IL-17 receptor and inhibits its interaction with IL-17 cytokines. These agents are commonly reserved for patients with moderate-to-severe cases after failure to control with first line therapies.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Taltz®	• Cosentyx® • Siliq®

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, Interleukin (IL)-17 Antibody/IL-17 Receptor Antagonists
- Age range: All appropriate MO HealthNet participants aged 18 years or older unless otherwise indicated

Approval Criteria

- Documented compliance on current therapy **OR**
- 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**
- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agent (6 months of therapy) **OR**
  - Documented ADE/ADR to preferred agent **OR**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Generic	Brand	Indication
Ixekizumab	Taltz®	• Ankylosing spondylitis • Non-radiographic axial spondyloarthritis • Plaque psoriasis (aged 6 or older) • Psoriatic arthritis
Secukinumab	Cosentyx®	• Ankylosing spondylitis • Non-radiographic axial spondyloarthritis • Plaque psoriasis **(aged 6 or older)** • Psoriatic arthritis
Brodalumab	Siliq®	• Plaque psoriasis

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: ☐ 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.
3. Siliq [package insert]. Bridgewater, NJ: Bausch Health US, LLC; 2020.
4. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Co; 2021.
5. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceutical; 2021.
6. Evidence-Based Medicine Analysis: “Targeted Immune Modulators (Biologics – DMARDS)”. UMKC-DIC; April 2021.

7. Evidence-Based Medicine and Fiscal Analysis: “Targeted Immune Modulators: Interleukin (IL)-17, -12/23 and -23 Inhibitors– Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.