SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, Interleukin (IL)-17 Antibody/IL-17 Receptor Antagonists, IL-23 Inhibitors and IL-23/IL-12 Inhibitors PDL Edit
First Implementation Date:	January 22, 2004
Proposed Date:	June 18, 2020
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 spondylarthritis while the IL-12 and IL-23 pathways are involved in Crohn's disease, ulcerative colitis and psoriasis. Though these agents have similar targets, they vary in mechanism of action and indication. The agents in this class are all subcutaneous injections except for Stelara® (ustekinumab) being IV in use for Crohn's disease and ulcerative colitis. 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® • Ilumya™ • Siliq® • Skyrizi™ • Stelara® • Tremfya®

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, IL-23 Inhibitors and IL-23/IL-12 Inhibitors
- 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**
- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agents **(6 months of therapy)**
  - Documented ADE/ADR to preferred agents **AND**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Generic	Brand	Indication
Brodalumab	Siliq®	• Plaque psoriasis
Guselkumab	Tremfya	• Plaque psoriasis
Ixekizumab	Taltz®	• Ankylosing spondylitis • **Non-radiographic axial spondyloarthritis** • Plaque psoriasis (aged 6 or older) • Psoriatic arthritis
Secukinumab	Cosentyx®	• Ankylosing spondylitis • Plaque psoriasis • Psoriatic arthritis
Tildrakizumab-asmn	Ilumya™	• Plaque psoriasis
Ustekinumab	Stelara®	• Crohn's disease • Plaque psoriasis (aged 12 or older) • Psoriatic Arthritis • Ulcerative colitis
Risankizumab	**Skyrizi™**	• **Plaque psoriasis**

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

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc; 2019.
5. Siliq [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2018.
6. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc; 2019.
7. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Co; 2020.
8. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceutical; 2020.
9. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc; 2020.
10. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc; 2020.
11. Evidence-Based Medicine Analysis: “Targeted Immune Modulators (Biologics – DMARDS)”. UMKC-DIC; April 2020.
12. 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; April 2020.