SmartPA Criteria Proposal

Drug/Drug Class:	Targeted Immune Modulators, IL-23 Inhibitors and IL-23/IL-12 Inhibitors PDL Edit
First Implementation Date:	October 14, 2021
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: 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 monoclonal antibodies within this class function by inhibiting the release of the pro-inflammatory cytokines and are commonly utilized to treat chronic autoimmune conditions such as Crohn's disease, plaque psoriasis, psoriatic arthritis, and ulcerative colitis. Ilumya® (tildrakizumab-asmn), Skyrizi® (risankizumab-rzza), and Tremfya® (guselkumab) are IL-23 antagonists while Stelara® (ustekinumab) is a dual IL-12 and IL-23 antagonist. All products in this class are dosed via either intravenous or subcutaneous injection and use is 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
• Ilumya® • Tremfya®	• Skyrizi® • Stelara®

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **Clinical Edit**

Setting & Population

- Drug class for review: Targeted Immune Modulators, IL-23 Inhibitors and IL-23/IL-12 Inhibitors
- 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) inhibitor (trial defined as duration of therapy with class not agent) **AND**
- 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 agents (6 months of therapy) **OR**
    - Documented ADE/ADR to preferred agents **OR**
- For treatment of Crohn's disease: adequate therapeutic 6 month trial of Entyvio
- Documentation of appropriate diagnosis and participant age range for requested agent:

Biologic Agent	Brand	Indication
guselkumab	Tremfya®	• Plaque psoriasis • Psoriatic arthritis
risankizumab	Skyrizi®	• Crohn's disease • Plaque psoriasis • Psoriatic arthritis
tildrakizumab-asmn	Ilumya®	• Plaque psoriasis
ustekinumab	Stelara®	• Crohn's disease • Plaque psoriasis (aged 6 or older) • Psoriatic arthritis (aged 6 or older) • Ulcerative colitis

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Maximum Dosing Limitation
STELARA 45 MG/0.5 ML VIAL	USTEKINUMAB	0.5 mL per claim
STELARA 45 MG/0.5 ML SYRINGE	USTEKINUMAB	0.5 mL per claim
STELARA 90 MG/ML SYRINGE	USTEKINUMAB	1 mL per claim

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: Targeted Immune Modulators: Interleukin-23 Inhibitors and Interleukin-23/Interleukin-12 Inhibitors”, Gainwell Technologies; Last updated May 10, 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.
- Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc.; December 2022.
- Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; September 2022.
- Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2023.
- Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2020.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.