

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
Revised Date:	May 19, 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: 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-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 administered via subcutaneous injections with the exception of Stelara® which is also available as an IV formulation for initiation of therapy in severely active 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
	<ul style="list-style-type: none"> • Ilumya® • Tremfya® 	<ul style="list-style-type: none"> • Skyrizi® • Stelara®

Type of Criteria:
 Increased risk of ADE
 Preferred Drug List
 Appropriate Indications
 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) 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) **OR**
 - Documented ADE/ADR to preferred agents **AND**
- Documentation of appropriate diagnosis and participant age range for requested agent:

Generic	Brand	Indication
Guselkumab	Tremfya®	<ul style="list-style-type: none"> • Plaque psoriasis • Psoriatic arthritis
Risankizumab	Skyrizi®	<ul style="list-style-type: none"> • Plaque psoriasis
Tildrakizumab-asmn	Ilumya®	<ul style="list-style-type: none"> • Plaque psoriasis
Ustekinumab	Stelara®	<ul style="list-style-type: none"> • Crohn's disease • Plaque psoriasis (aged 6 or older) • Psoriatic arthritis • 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 fill
STELARA 45 MG/0.5 ML SYRINGE	USTEKINUMAB	0.5 mL per fill
STELARA 90 MG/ML SYRINGE	USTEKINUMAB	1 mL per fill
STELARA 130 MG/26 ML VIAL	USTEKINUMAB	104 mL per fill

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. Evidence-Based Medicine Analysis: "Targeted Immune Modulators (Biologics – DMARDs)". UMKC-DIC; April 2021.
2. 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.
3. USPDI, Micromedex; 2021.
4. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.

SmartPA PDL Proposal Form

© 2022 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

5. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc; 2020.
6. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc; 2020.
7. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc; 2021.
8. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc; 2020.