

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Targeted Immune Modulators, IL-23 Inhibitors and IL-23/IL-12 Inhibitors PDL Edit
<b>First Implementation Date:</b>	January 22, 2004
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<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<sup>®</sup> 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.

<b>Program-Specific Information:</b>	<b>Preferred Agents</b>	<b>Non-Preferred Agents</b>
	<ul style="list-style-type: none"> <li>• Ilumya<sup>®</sup></li> <li>• Tremfya<sup>®</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Skyrizi<sup>®</sup></li> <li>• Stelara<sup>®</sup></li> </ul>

**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**

*SmartPA PDL Proposal Form*

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- 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"> <li>• Plaque psoriasis</li> <li>• Psoriatic arthritis</li> </ul>
Risankizumab	Skyrizi®	<ul style="list-style-type: none"> <li>• Plaque psoriasis</li> </ul>
Tildrakizumab-asmn	Ilumya®	<ul style="list-style-type: none"> <li>• Plaque psoriasis</li> </ul>
Ustekinumab	Stelara®	<ul style="list-style-type: none"> <li>• Crohn's disease</li> <li>• Plaque psoriasis (aged 6 or older)</li> <li>• Psoriatic arthritis</li> <li>• Ulcerative colitis</li> </ul>

## 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:  
MedWatch Form:

  


Progress Notes:  
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. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc; 2020.
4. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc; 2020.
5. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc; 2021.
6. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc; 2020.
7. Evidence-Based Medicine Analysis: "Targeted Immune Modulators (Biologics – DMARDS)". UMKC-DIC; April 2021.
8. 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.