



## Cytokine and CAM Antagonists: Interleukin-23 (IL-23) and IL-12/IL-23 Inhibitors Utilization Management Criteria

<b>Therapeutic Class:</b>	Cytokine and CAM Antagonists: Interleukin-23 (IL-23) and IL-12/IL-23 Inhibitors
<b>Non-Preferred Agents:</b>	<p>Ilumya (tildrakizumab-asmn), Omvoh (mirikizumab-mrkz), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)</p> <p><b>Ustekinumab Products</b></p> <p>Imuldosa (ustekinumab-srlf)            Otulfi (ustekinumab-aaaz)            Pyzchiva (ustekinumab-ttwe) intravenous vial            Selarsdi (ustekinumab-aekn) subcutaneous vial            Starjemza (Ustekinumab-hmny)            Stelara (ustekinumab)            Yesintek (ustekinumab-kfca)            Ustekinumab            Ustekinumab-aekn            Ustekinumab-ttwe</p>
<b>Preferred Agents:</b>	<p><b>Ustekinumab Products</b></p> <p>Steqeyma (ustekinumab-stba) intravenous vial and subcutaneous syringe            Pyzchiva (ustekinumab-ttwe) subcutaneous vial and subcutaneous syringe            Selarsdi (ustekinumab-aekn) intravenous vial and subcutaneous syringe</p>
<b>Implementation Date:</b>	1/1/2026
<b>Prepared For:</b>	CT
<b>PDL Status:</b>	Non-preferred Agents
<b>Purpose:</b>	<p>The interleukin (IL)-23 inhibitors are monoclonal antibodies that bind specifically to the p19 subunit of IL-23 and inhibit the release of proinflammatory cytokines and chemokines. The IL-12/23 inhibitor, ustekinumab, is a monoclonal antibody that binds to the p40 subunit, used by both the IL-12 and IL-23 cytokines, and disrupts cytokine cascade thought to be involved in chronic inflammation. The IL-23 inhibitors, guselkumab, mirikizumab, risankizumab, and tildrakizumab, and the IL-23/IL-12 inhibitor, ustekinumab, are indicated for the treatment of a variety of conditions, including plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative</p>

colitis as summarized for each medication in table 1. All agents are administered by either subcutaneous or intravenous injection. Only ustekinumab and guselkumab are approved for use in pediatric patients for the treatment of psoriatic arthritis and plaque psoriasis in children  $\geq 6$  years of age. Some warnings and precautions vary among the IL-23 and IL-12/23 inhibitors, but all agents have warnings regarding increased risks for serious infection, including tuberculosis.

**Table 1. Interleukin-23 (IL-23) and IL-12/IL-23 Inhibitors**

Generic Name	Brand Name	Approved Indications	Route of Administration	Biosimilar Availability
Guselkumab	Tremfya <sup>®</sup>	PsO, PsA, UC, CD	SC, IV	No
Mirikizumab-mrkz	Omvoh <sup>™</sup>	UC, CD	SC, IV	No
Risankizumab-rzaa	Skyrizi <sup>®</sup>	PsO, PsA, UC, CD	SC, IV	No
Tildrakizumab-asmn	Ilumya <sup>®</sup>	PsO	SC	No
Ustekinumab	Stelara <sup>®</sup>	PsO, PsA, UC, CD	SC, IV	Yes
Ustekinumab-aaaz	Otulfi <sup>™±</sup>			N/A
Ustekinumab-hmny	Starjemza			
Ustekinumab-srlf	Imuldosa <sup>±</sup>			N/A
Ustekinumab-ttwe	Pyzchiva <sup>®±</sup>			N/A
Ustekinumab-aekn	Selarsdj <sup>™±</sup>			N/A
Ustekinumab-stba	Steqeyma <sup>®±</sup>			N/A
Ustekinumab-kfce	Yesintek <sup>™±</sup>			N/A

Abbreviations: Abbreviations: CD, Crohn's disease; IV, intravenous; PsA, psoriatic arthritis; PsO, plaque psoriasis; SC, subcutaneous; UC, ulcerative colitis.

<sup>±</sup>FDA approved biosimilar to Stelara<sup>®</sup>

**All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes.**

**General Approval Criteria**

- Claim is for a preferred agent **OR**
- Requested agent is **NOT** used in combination with other targeted immunomodulators **AND**
- Patient does **NOT** have active TB, or other active infection prior to initiation **AND**
- Requested quantity in accordance with FDA approved product labeling **AND**

**Initial Therapy – All the following must be met:**

**For Moderate to Severe Crohn's Disease OR Ulcerative Colitis (Omvoh, Skyrizi, Tremfya)**

- Prescribed by or in consultation with a gastroenterologist
- Documented diagnosis (listed above)
- Trial and failure of a preferred tumor necrosis factor inhibitor (TNFi) or preferred ustekinumab biosimilar **OR** documented adverse event/adverse drug reaction or contraindication

### For Active Psoriatic Arthritis (Skyrizi, Tremfya)

- Prescribed by or in consultation with a rheumatologist or dermatologist
- Documented diagnosis (listed above)
- Trial and failure of a preferred tumor necrosis factor inhibitor (TNFi) or preferred ustekinumab biosimilar **OR** documented adverse event/adverse drug reaction or contraindication

### For Moderate to Severe Plaque Psoriasis (Ilumya, Skyrizi, Tremfya)

- Prescribed by or in consultation with a dermatologist
- Documented diagnosis (listed above)
- Patient is a candidate for systemic therapy or phototherapy
- Trial and failure of a preferred tumor necrosis factor inhibitor (TNFi) or preferred ustekinumab biosimilar **OR** documented adverse event/adverse drug reaction or contraindication

### For Stelara and non-preferred biosimilars

- Prescribed by or in consultation with a specialist familiar with the treated disease state
- Prescribed for an FDA approved indication
- Trial and failure of a preferred ustekinumab formulation **OR** documented adverse event/adverse drug reaction to a preferred formulation

### Non-preferred Age Limitations:

- Tremfya
  - For ulcerative colitis and Crohn's disease: 18 years and older
  - For plaque psoriasis and psoriatic arthritis: 6 years and older (pediatric patients must weigh 40 kg or more)
- Ilumya, Omvoh, Skyrizi: 18 years and older
- Stelara and non-preferred biosimilars
  - For ulcerative colitis and Crohn's disease: 18 years and older
  - For plaque psoriasis and psoriatic arthritis: 6 years and older

### Initial PA length: 1 year

### Exclusion Criteria: Approval criteria not met

**Continuation Therapy:** Documented continued clinical benefit **AND** Documented compliance on current therapy regimen (*Exceptions: Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred Ustekinumab formulations*)

### Continuation Length: 1 year

### References:

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## Revision History

Date	Version	Revisions
11/21/25	V1	Document approved by DSS
3/23/26	V2	Updates made to trial and failure requirements, updates made to Stelara coverage criteria