

- 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®	<ul style="list-style-type: none"> • Plaque psoriasis • Psoriatic arthritis
risankizumab	Skyrizi®	<ul style="list-style-type: none"> • Crohn's disease • Plaque psoriasis • Psoriatic arthritis
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 (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:
 MedWatch Form:

Progress Notes:
 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.