

# Clinical Criteria

<b>Subject:</b>	Monoclonal Antibodies to Interleukin-23		
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## Overview

This document addresses the use of monoclonal antibodies which bind to the interleukin-23 (IL-23) cytokine and disrupt its interaction with the IL-23 receptor thereby inhibiting the release of proinflammatory cytokines and chemokines. IL-23 inhibitors are approved for the treatment of plaque psoriasis. Agents addressed in this clinical criteria document include:

- Ilumya (tildrakizumab-asmn)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)

**Plaque Psoriasis (otherwise known as psoriasis vulgaris):** The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) published joint guidelines on the management and treatment of psoriasis with biologics. The guidelines do not include a treatment algorithm or compare biologics to each other or conventional therapy. The guideline notes that patients with mild-moderate disease may be adequately controlled with topical therapy and/or phototherapy while moderate to severe disease may necessitate treatment with a biologic. Moderate to severe disease is defined as involvement in > 3% of body surface area (BSA) or involvement in sensitive areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). TNFi biologics, ustekinumab, IL17 inhibitors, and IL23 inhibitors are all recommended as monotherapy treatment options for adult patients with moderate to severe plaque psoriasis.

**Psoriatic Arthritis:** The American College of Rheumatology (ACR) guidelines recommend that initial treatment of patients with active severe PsA or concomitant psoriasis should include a TNFi biologic over an oral small molecule (OSM; including methotrexate, sulfasalazine, cyclosporine, leflunomide, and apremilast). For initial therapy, OSMs are preferred over IL-17 and ustekinumab; and may be considered over TNFi biologics in mild to moderate disease without comorbid conditions or in those who prefer oral therapy. Recommendations involving biologics over OSMs as first line therapy are conditional and based on low quality evidence. Evidence cited includes indirect comparisons of placebo-controlled trials, studies with open-label design, and extrapolation from studies in plaque psoriasis. Furthermore, most pivotal trials for TNFi biologics included a study population that were DMARD experienced. Overall, there is a lack of definitive evidence for the safety and efficacy of biologic drugs over conventional therapy for the initial treatment of most patients with psoriatic arthritis. The ACR guidelines precede FDA approval of guselkumab for psoriatic arthritis.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Ilumya (tildrakizumab-asmn)

**Initial Request** requests for Ilumya (tildrakizumab-asmn) may be approved for the following:

- I. Plaque psoriasis (Ps) when each of the following criteria are met:
  - A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
    1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**

2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
- B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate).

Continuation requests for Ilumya (tildrakizumab-asmn) may be approved if the following criterion is met:

- I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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Requests for Ilumya (tildrakizumab-asmn) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. In combination with JAK inhibitors, apremilast, other IL-23 inhibitors, or other biologic drugs (such as TNF antagonists or ustekinumab) or phototherapy; **OR**
- III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
- IV. Prior to initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating tildrakizumab-asmn(unless switching therapy from another targeted immune modulator and no risk factors).

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### Skyrizi (risankizumab-rzaa)

Initial Rrequests for Skyrizi (risankizumab-rzaa) may be approved for the following:

- II. Plaque psoriasis (Ps) when each of the following criteria are met:
  - A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
    1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
    2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate).

Continuation requests for Skyrizi (risankizumab-rzaa) may be approved if the following criterion is met:

- I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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Requests for Skyrizi (risankizumab-rzaa) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. In combination with JAK inhibitors, apremilast, other IL-23 inhibitors, or other biologic drugs (such as TNF antagonists or ustekinumab) or phototherapy; **OR**
- III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
- IV. Prior to initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating risankizumab-rzaa(unless switching therapy from another targeted immune modulator and no risk factors).

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### Tremfya (guselkumab)

Initial Rrequests for Tremfya (guselkumab) may be approved for the following:

- I. Plaque psoriasis (Ps) when each of the following criteria are met:
  - A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
    1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
    2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate).
- OR**
- II. Psoriatic arthritis (PsA) when each of the following criteria are met:
  - A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
  - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] or a tumor necrosis factor (TNF) antagonist.

Continuation requests for Tremfya (guselkumab) may be approved if the following criterion is met:

- I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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Requests for Tremfya (guselkumab) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. In combination with JAK inhibitors, apremilast, other IL-23 inhibitors, or other biologic drugs (such as TNF antagonists or ustekinumab) or phototherapy; **OR**
- III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**

- IV. Prior to initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating guselkumab(unless switching therapy from another targeted immune modulator and no risk factors).

## Quantity Limits

### Ilumya (tildrakizumab-asmn) Quantity Limit

Drug	Limit
Ilumya (tildrakizumab-asmn) 100 mg/mL	1 prefilled syringe per 84 days (12 weeks)
Override Criteria	
*Initiation of therapy for Plaque Psoriasis (Ps): May approve up to 1 additional syringe (100 mg/mL) in the first 28 days (4 weeks) of treatment.	

### Skyrizi (risankizumab-rzaa) Quantity Limit

Drug	Limit
Skyrizi (risankizumab-rzaa) 75 mg/ 0.83 mL	2 prefilled syringes [1 carton] per 84 days (12 weeks)
Override Criteria	
*Initiation of therapy for Plaque Psoriasis (Ps): May approve up to 2 additional syringes (75 mg/ 0.83 mL) [1 carton] in the first 28 days (4 weeks) of treatment.	

### Tremfya (guselkumab) Quantity Limit

Drug	Limit
Tremfya (guselkumab) 100 mg/mL	1 prefilled syringe/autoinjector per 56 days (8 weeks)
Override Criteria	
*Initiation of therapy for Plaque Psoriasis (Ps) or Psoriatic Arthritis (PsA): May approve up to 1 additional syringe (100 mg/mL) in the first 28 days (4 weeks) of treatment.	

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### HCPCS

<b>J1628</b>	Injection, guselkumab, 1 mg [Tremfya]
<b>J3245</b>	Injection, tildrakizumab, 1 mg [Ilumya]
<b>J3490</b>	Unclassified drugs [when specified as Skyrizi]
<b>J3590</b>	Unclassified biologics [when specified as Skyrizi]

### ICD-10 Diagnosis

<b>L40.0</b>	Psoriasis vulgaris
<b>L40.1</b>	Generalized pustular psoriasis
<b>L40.2</b>	Acrodermatitis continua
<b>L40.3</b>	Pustulosis palmaris et plantaris
<b>L40.4</b>	Guttate psoriasis
<b>L40.50-L40.59</b>	Arthropathic psoriasis
<b>L40.8</b>	Other psoriasis
<b>L40.9</b>	Psoriasis, unspecified

## Document History

Revised: 11/20/2020

Document History:

- 11/20/2020 – Annual Review: Add continuation of use section; add additional examples of combination use for clarity; update tuberculosis testing language. Coding Reviewed: No changes.
- 08/21/2020 – Select Review: Add new psoriatic arthritis indication to Tremfya clinical criteria; update quantity limit override. Coding Reviewed: Added ICD-10CM-L40.50-L40.59
- 11/15/2019 – Annual Review: Update definition of moderate psoriasis using BSA based on guidelines; update combination therapy criteria for consistency with other agents; wording and formatting changes. Coding reviewed: No Changes.
- 09/23/2019 - Administrative update to add drug specific quantity limit.
- 05/17/2019 – Select Review: Add new clinical criteria and quantity limit for new agent Skyrizi. Update Tremfya quantity limit to include new autoinjector formulation per label. Coding Review: Added J3490 and J3590 for Skyrizi.
- 11/16/2018 – Annual Review: Initial P&T review of Monoclonal Antibodies to Interleukin-23 Clinical Guideline. Update clinical criteria to delete requirement agent is being used “to reduce signs and symptoms, maintain clinical response”, etc. Wording and formatting changes to criteria for consistency. HCPCS and ICD-10 Coding Review: Deleted C9029, J3490, J3590. Added J1628, J3245.

## References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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