

Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Monoclonal Antibodies to Interleukin-23 [Ilumya® (tildrakizumab-asmn), Skyrizi IV® (risankizumab-rzaa), Tremfya® IV (guselkumab)]	MP-RX-FP-61-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth

Service Category

- | | |
|--|---|
| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Part B DRUG |

Service Description

This document addresses the use of **Monoclonal Antibodies to Interleukin-23**, approved by the Food and Drug Administration (FDA) for the treatment of plaque psoriasis, psoriatic arthritis, Chron's disease, and ulcerative colitis.

Background Information

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 IV (guselkumab)
- Skyrizi IV (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). Tumor necrosis factor inhibitor (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

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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 and risankizumab for psoriatic arthritis.

Crohn's Disease: According to the American Gastrointestinal Association clinical practice guidelines, evidence supports the use of methotrexate, corticosteroids, TNFi +/- immunomodulator, ustekinumab, or vedolizumab for induction of remission. Among the biologics, infliximab, adalimumab, ustekinumab, or vedolizumab are recommended or suggested over certolizumab for induction of remission. Evidence supports biologic agents, thiopurines, and methotrexate for maintenance of remission. Ustekinumab and vedolizumab are options for individuals with primary nonresponse to initial treatment with TNFi. Adalimumab, ustekinumab, or vedolizumab may be used in cases where an individual previously responded to infliximab and then lost response (secondary nonresponse). The AGA guidelines precede FDA approval of risankizumab for CD.

Ulcerative Colitis: For those with moderately to severely active disease, the American College of Gastroenterology (ACG) guidelines strongly recommend induction of remission using oral budesonide MMX, oral systemic corticosteroids, TNFi, tofacitinib or vedolizumab (moderate to high quality evidence). The American Gastroenterological Association (AGA) guidelines define moderate to severe UC as those who are dependent on or refractory to corticosteroids, have severe endoscopic disease activity, or are at high risk of colectomy. AGA strongly recommends biologics (TNFi, vedolizumab, or ustekinumab) or tofacitinib over no treatment in induction and maintenance of remission (moderate quality of evidence). For biologic-naïve individuals, Infliximab or vedolizumab are conditionally recommended over adalimumab for induction of remission (moderate quality evidence). Guidelines precede FDA approval of IL23 inhibitors for UC.

Approved Indications

Monoclonal Antibodies targeting Interleukin-23 indications have drug specific indications:

- Plaque psoriasis (Ilumya, Tremfya, and Skyrizi)
- Psoriatic Arthritis (Tremfya and Skyrizi)
- Crohn's Disease (Skyrizi)
- Ulcerative Colitis (Tremfya)

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Other Uses
i. N/A

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPSC	Description
J1628	Injection, guselkumab, 1 mg [Tremfya]
J3245	Injection, tildrakizumab, 1 mg [Ilumya]
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg [Skyrizi]

ICD-10	Description
K50.0-K50.019	Crohn's disease of small intestine (Skyrizi)
K50.1-K50.119	Crohn's disease of large intestine (Skyrizi)
K50.8-K50.819	Crohn's disease of both small and large intestine (Skyrizi)
K50.9-K50.919	Crohn's disease, unspecified (Skyrizi)
K51.00-K51.919	Ulcerative Colitis (Skyrizi, Tremfya)
L40.0	Psoriasis vulgaris
L40.1	Generalized pustular psoriasis (Skyrizi, Tremfya, Ilumya)
L40.2	Acrodermatitis continua (Skyrizi, Tremfya, Ilumya)
L40.3	Pustulosis palmaris et plantaris (Skyrizi, Tremfya, Ilumya)
L40.4	Guttate psoriasis (Skyrizi, Tremfya, Ilumya)
L40.50	Arthropathic psoriasis, unspecified (Skyrizi, Tremfya, Ilumya)
L40.51	Distal interphalangeal psoriatic arthropathy (Skyrizi, Tremfya, Ilumya)
L40.52	Psoriatic arthritis mutilans (Skyrizi, Tremfya, Ilumya)
L40.53	Psoriatic spondylitis (Skyrizi, Tremfya, Ilumya)
L40.54	Psoriatic juvenile arthropathy (Skyrizi, Tremfya, Ilumya)
L40.59	Other psoriatic arthropathy (Skyrizi, Tremfya, Ilumya)
L40.8	Other psoriasis (Skyrizi, Tremfya, Ilumya)
L40.9	Psoriasis, unspecified (Skyrizi, Tremfya, Ilumya)

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Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria

Tildrakizumab-asmn (Ilumya®)

A. Criteria for Initial Approval

Initial 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).

OR

 - C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate.

B. Criteria for Continuation of Therapy

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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C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Requests for Ilumya (tildrakizumab-asmn) may not be approved for the following:
 - A. In combination with phototherapy;
 - OR**
 - B. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, or any of the following biologic immunomodulators: TNF antagonists, other IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab;
 - OR**
 - C. Tuberculosis, other active serious infections, or a history of recurrent infections;
 - OR**
 - D. If 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 (unless switching therapy from another targeted immune modulator and no new risk factors);
 - OR**
 - E. When the above criteria are not met and for all other indications.

D. Authorization Duration

- i. Initial Approval Duration: Up to 12 months
- ii. Reauthorization Approval Duration: Up to 12 months

Risankizumab-rzaa (Skyrizi IV®)

A. Criteria for Initial Approval

Initial requests for Skyrizi (risankizumab-rzaa) 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**

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<p>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);</p> <p>OR</p> <p>C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;</p> <p>OR</p>	
ii.	<p>Psoriatic arthritis (PsA) when each of the following criteria are met:</p> <p>A. Individual is 18 years of age or older with moderate to severe PsA; AND</p> <p>B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)];</p> <p>OR</p> <p>C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;</p> <p>OR</p>
iii.	<p>Crohn's Disease (CD) when each of the following criteria are met:</p> <p>A. Individual is 18 years of age or older with moderate to severe CD; AND</p> <p>B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]).</p> <p>OR</p>
iv.	<p>Ulcerative colitis (UC) when the following criteria are met:</p> <p>A. For individuals requesting intravenous induction doses:</p> <ol style="list-style-type: none"> Individual is 18 years of age or older with moderate to severe UC; AND Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); <p>OR</p> <ol style="list-style-type: none"> Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines; <p>OR</p> <p>B. For individuals requesting subcutaneous maintenance therapy:</p> <ol style="list-style-type: none"> Individual is 18 years of age or older with moderate to severe UC; AND Individual has completed the intravenous induction doses with Skyrizi and will be using subcutaneous Skyrizi for maintenance therapy.

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B. Criteria for Continuation of Therapy

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

- i. Individual is 18 years of age or older with moderate to severe UC; **AND**
- ii. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

C. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Requests for Skyrizi (risankizumab-rzaa) may not be approved for the following:
 - A. In combination with phototherapy;
OR
 - B. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, or any of the following biologic immunomodulators: TNF antagonists, other IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab;
OR
 - C. Tuberculosis, other active serious infections, or a history of recurrent infections;
OR
 - D. If 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 (unless switching therapy from another targeted immune modulator and no new risk factors);
OR
 - E. When the above criteria are not met and for all other indications.

D. Authorization Duration

- i. Initial Approval Duration: Up to 12 months
- ii. Reauthorization Approval Duration: Up to 12 months

Guselkumab (Tremfya® IV)

A. Criteria for Initial Approval

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

- i. Plaque psoriasis (Ps) when each of the following criteria are met:

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<p>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):</p> <ol style="list-style-type: none"> 1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); <p>OR</p> <ol style="list-style-type: none"> 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 <p>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);</p> <p>OR</p> <p>C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;</p> <p>OR</p>	
ii.	<p>Psoriatic arthritis (PsA) when each of the following criteria are met:</p> <ol style="list-style-type: none"> 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, cyclosporine or leflunomide)]; <p>OR</p> <p>C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;</p> <p>OR</p>
iii.	<p>Ulcerative colitis (UC) when the following criteria are met:</p> <ol style="list-style-type: none"> A. For individuals requesting intravenous induction doses: <ol style="list-style-type: none"> 1. Individual is 18 years of age or older with moderate to severe UC; AND 2. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); <p>OR</p> 3. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines; <p>OR</p> B. For individuals requesting subcutaneous maintenance therapy: <ol style="list-style-type: none"> 1. Individual is 18 years of age or older with moderate to severe UC; AND 2. Individual has completed the intravenous induction doses with Tremfya and will be using subcutaneous Tremfya for maintenance therapy

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B. Criteria for Continuation of Therapy

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

- i. Individual has been receiving and is maintained on a stable dose of Tremfya; **AND**
- ii. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Requests for Tremfya (guselkumab) may not be approved for the following:
 - A. In combination with phototherapy;
OR
 - B. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, or any of the following biologic immunomodulators: TNF antagonists, other IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab;
OR
 - C. Tuberculosis, other active serious infections, or a history of recurrent infections;
OR
 - D. If 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 (unless switching therapy from another targeted immune modulator and no new risk factors);
OR
 - E. When the above criteria are not met and for all other indications.

D. Authorization Duration

- i. Initial Approval Duration: Up to 12 months
- ii. Reauthorization Approval Duration: Up to 12 months

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Ilumya® (tildrakizumab-asmn) Quantity Limit

Drug	Limit
Ilumya (tildrakizumab-asmn) 100 mg/mL	1 prefilled syringe per 84 days (12 weeks)
Exceptions	
*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® IV (risankizumab-rzaa) Quantity Limit

Drug	Limit
Skyrizi (Risankizumab-rzaa) 600 mg/10 mL single-dose vial	6 vials total to last 12 weeks
Exceptions	
None	

Tremfya® IV (guselkumab) Quantity Limit

Drug	Limit
Tremfya (guselkumab) 200 mg/20 mL single-dose vial	3 vials total to last 12 weeks
Exceptions	
None	

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Reference Information

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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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Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Choose an item.		Click or tap to enter a date.	Click or tap to enter a date.
Annual Review. 8/16/2024	Specify IV formulations included in this medical policy for Tremfya and Skyrizi. Added sections: Approved Indications, Other Uses. Update Background Information, Clinical Criteria (added approval duration Update Tremfya clinical criteria with new indication for ulcerative colitis; add quantity limit for new Tremfya dosages. Coding Reviewed: Designate Skyrizi for Chron's, UC, and Psoriasis indications, Tremfya for UC and Psoriasis indications, and Ilumya for Psoriasis indications in parentheses next to diagnosis descriptions. Update Skyrizi clinical criteria to include new indication for Ulcerative Colitis; update Skyrizi quantity limit to remove obsolete strength, include new 90 mg strength with override, and increase vial quantity limit for UC induction dosing. Coding Reviewed: Add ICD-10-CM L40.1, L40.2, L40.3, L40.4, L40.54 and changed naming of L40.0 from Plaque psoriasis to Psoriasis vulgaris; Removed HCPCS J3490, J3590, C9399. Removed HCPCS J3590, C9168. Update wording and formatting.	2/24/2025	3/6/2025
Policy Inception 8/16/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023