Medical Drug Clinical Criteria

Subject:	Monoclonal Antibodies to Interleukin-23		
Document #:	CC-0050	**Publish Date**:	05/01/2025
Status:	Revised	**Last Review Date**:	02/21/2025

Table of Contents

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:

- Omvoh (mirikizumab-mrkz)
- 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). 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 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 IL23 inhibitors 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.

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 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, or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate.

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

I. Individual has been receiving and is maintained on a stable dose of Ilumya; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, etrasimod, 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**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
IV. 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**
V. When the above criteria are not met and for all other indications.

Omvoh (mirikizumab-mrkz)

Initial requests for Omvoh (mirikizumab-mrkz) may be approved for the following:

I. Ulcerative colitis (UC) when the following criteria are met:
   A. For individuals requesting intravenous induction doses:
      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]); **OR**
      3. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

   OR

   B. For individuals requesting subcutaneous maintenance therapy:
      1. Individual is 18 years of age or older with moderate to severe UC; **AND**
      2. Individual has completed the intravenous induction doses with Omvoh and will be using subcutaneous Omvoh for maintenance therapy;

OR

II. Crohn's Disease (CD) when each of the following criteria are met:
   A. For individuals requesting intravenous induction doses:
      1. Individual is 18 years of age or older with moderate to severe CD; **AND**
      2. Individual has had an inadequate response to or is intolerant of conventional therapy (such as systemic corticosteroids, or immunosuppressants [such as thiopurines or methotrexate]); **OR**
      3. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;

   OR

   B. For individuals requesting subcutaneous maintenance therapy:
      1. Individual is 18 years of age or older with moderate to severe CD; **AND**
      2. Individual has completed the intravenous induction doses with Omvoh and will be using subcutaneous Omvoh for maintenance therapy.

Continuation requests for Omvoh (mirikizumab-mrkz) [intravenous and subcutaneous] may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Omvoh; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Omvoh (mirikizumab-mrkz) may not be approved for the following:

I. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, etrasimod, 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**
II. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
III. 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**
IV. When the above criteria are not met and for all other indications.

Skyrizi (risankizumab-rzaa)

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**
   B. Individual has had an inadequate response to, or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and 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, or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

III. Crohn's Disease (CD) when each of the following criteria are met:
   A. For individuals requesting intravenous induction doses:
      1. Individual is 18 years of age or older with moderate to severe CD; **AND**
      2. Individual has had an inadequate response to, or is intolerant of conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]); **OR**
      3. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;

   OR

   B. For individuals requesting subcutaneous maintenance therapy:
      1. Individual is 18 years of age or older with moderate to severe CD; **AND**
      2. Individual has completed the intravenous induction doses with Skyrizi and will be using subcutaneous Skyrizi for maintenance therapy;

OR

IV. Ulcerative colitis (UC) when the following criteria are met:
   A. For individuals requesting intravenous induction doses:
      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]); **OR**
      3. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

   OR

   B. For individuals requesting subcutaneous maintenance therapy:
      1. Individual is 18 years of age or older with moderate to severe UC; **AND**
      2. Individual has completed the intravenous induction doses with Skyrizi and will be using subcutaneous Skyrizi for maintenance therapy.

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

I. Individual has been receiving and is maintained on a stable dose of Skyrizi; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, etrasimod, 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**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
IV. 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**
V. When the above criteria are not met and for all other indications.

Tremfya (guselkumab)

Initial requests 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, or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and 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, or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

III. Ulcerative colitis (UC) when the following criteria are met:
   A. For individuals requesting intravenous induction doses:
      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]); **OR**
      3. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

   OR

   B. For individuals requesting subcutaneous maintenance therapy:
      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.

Continuation requests for Tremfya (guselkumab) may be approved if the following criteria are 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.

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

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, etrasimod, 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**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
IV. 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**
V. When the above criteria are not met and for all other indications.

Step Therapy

Note: When a monoclonal antibody to interleukin-23 is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferred[1] agent or agents.

Omvoh Step Therapy

A list of preferred targeted immune modulator(s) is available here.

Commercial requests for diagnosis of Crohn's Disease and Ulcerative Colitis:

Requests for Omvoh may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Omvoh;
OR
II. Individual has had a trial and inadequate response or intolerance to TWO preferred agent(s).

[1]Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

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.	

Omvoh (mirikizumab-mrkz)

Drug	Limit
Omvoh (mirikizumab-mrkz) 100 mg/mL prefilled pen/syringe	2 pens/syringes per 28 days (4 weeks)
Omvoh (mirikizumab-mrkz) 200 mg/2 mL + 100 mg/mL prefilled pen/syringe	2 pens/syringes [1 carton] per 28 days (4 weeks)
Omvoh (mirikizumab-mrkz) 300 mg/15 mL single-dose vial	9 vials total to last 12 weeks

Skyrizi (risankizumab-rzaa) Quantity Limit

Drug	Limit
Skyrizi (risankizumab-rzaa) 90 mg/mL syringe^	2 prefilled syringes per 56 days (8 weeks)
Skyrizi (risankizumab-rzaa) 150 mg/mL syringe/pen*	1 prefilled syringe/pen [1 carton] per 84 days (12 weeks)
Skyrizi (Risankizumab-rzaa) 180 mg/ 1.2 mL prefilled cartridge with on-body injector	1 kit per 56 days (8 weeks)
Skyrizi (Risankizumab-rzaa) 360 mg/ 2.4 mL prefilled cartridge with on-body injector	1 kit per 56 days (8 weeks)
Skyrizi (Risankizumab-rzaa) 600 mg/ 10 mL single-dose vial	6 vials total to last 12 weeks
Override Criteria	
*Initiation of therapy for Plaque Psoriasis (Ps) or Psoriatic Arthritis (PsA): May approve 1 additional carton [one 150 mg pen/syringe] in the first 28 days (4 weeks) of treatment. ^Requests for up to 4 prefilled syringes per 56 days (8 weeks) may be approved if the following criteria are met: I. Information has been provided for the clinical necessity of the prefilled pen and why the individual is unable to use the 360 mg prefilled cartridge with on-body injector.	

Tremfya (guselkumab) Quantity Limit

Drug	Limit
Tremfya (guselkumab) 100 mg/mL pen/syringe	1 prefilled pen/syringe per 56 days (8 weeks)
Tremfya (guselkumab) 200 mg/2 mL pen/syringe	1 pen/syringe per 28 days (4 weeks)
Tremfya (guselkumab) 200 mg/20 mL single-dose vial	3 vials total to last 12 weeks

Override Criteria
*Initiation of therapy for Plaque Psoriasis (Ps) or Psoriatic Arthritis (PsA): May approve up to 1 additional pen/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

J1628	Injection, guselkumab, 1 mg [Tremfya]
J3245	Injection, tildrakizumab, 1 mg [Ilumya]
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg [Skyrizi]
J2267	Injection, mirikizumab-mrkz, 1 mg [Omvoh]

ICD-10 Diagnosis

K50.00-K50.919	Crohn's disease of small intestine (Skyrizi, Omvoh)
K51.00-K51.919	Ulcerative Colitis (Omvoh, Skyrizi, Tremfya)
L40.0	Plaque vulgaris (Skyrizi, Tremfya, Ilumya)
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-L40.59	Arthropathic psoriasis, unspecified (Skyrizi, Tremfya)
L40.8	Other psoriasis (Skyrizi, Tremfya, Ilumya)
L40.9	Psoriasis, unspecified (Skyrizi, Tremfya, Ilumya)

Document History

Revised: 2/21/2025
Document History:

- 05/01/2025 – Step therapy table updates.
- 2/21/2025 – Select Review: Update Omvoh clinical criteria with new indication for Crohn's disease; add quantity limit for new strength; increase quantity limit for vials. Coding Reviewed: Consolidated individual code ranges for Crohn's disease into a single range K50.00-K50.919 and updated description. Added Omvoh to K50.00-K50.919. Consolidated individual codes for arthropathic psoriasis into one range L40.50-L40.59. Removed Ilumya from L40.50-L40.59.
- 11/15/2024 – Annual Review: Update and clarify quantity limits based on approved dosage forms. 09/09/2024 – Select Review: 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, Omvoh for UC indications, and Ilumya for Psoriasis indications in parentheses next to diagnosis descriptions. Step therapy table updates. Coding reviewed: No changes.
- 08/16/2024 – Select Review: 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. Step therapy table updates. Coding Reviewed: Ulcerative Colitis indication already in document. 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.
- 07/01/2024 – Add new step therapy table.
- 11/17/2023 – Annual Review: Add clinical criteria and quantity limits to new agent Omvoh; add etrasimod to combination use exclusion for consistency; update contraindication to prior therapy language for clarity; update Crohn's disease criteria to separate criteria for IV induction dose or subcutaneous therapy; clarify repeat TB testing requirements; add continuation of use language; wording and formatting updates. Coding Reviewed: Added J3590 for Omvoh. Added ICD-10-DM K51.00-K51.919 (Omvoh). Removed HCPCS J3490, J3590, C9399. Effective 4/1/24 Added HCPCS C9168 for Omvoh. Effective 7/1/2024 Added HCPCS J2267 for Omvoh. Removed HCPCS J3590, C9168.
- 11/18/2022 – Annual Review: Update combination exclusion list to include additional agents and specify biologic immunomodulators; include additional conventional therapy examples per guidelines; add quantity limit for new Skyrizi

dosage form; wording and formatting updates. Coding Reviewed: Added HCPCS C9399. Effective 1/1/2023 Added HCPCS J2327 for Skyrizi. Added ICD-10-CM K50.00-K50.019, K50.10-K50.119, K50.80-K50.819, K50.90-K50.919.

- 08/19/2022 – Select Review: Add new Crohn's disease indication to Skyrizi clinical criteria; add quantity limit for new dosage forms of Skyrizi. Coding Reviewed: Added wording change to L40.0. Removed ICD-10-CM L40.1, L40.2, L40.3, L40.4, L40.50-L40.59. Added ICD-10-CM L40.50, L40.51, L40.52, L40.53, L40.59.
- 08/19/2022 – Select Review: Add new Crohn's disease indication to Skyrizi clinical criteria; add quantity limit for new dosage forms of Skyrizi.
- 02/25/2022 – Select Review: Add new psoriatic arthritis indication to Skyrizi clinical criteria and quantity limit; wording and formatting changes. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: Clarify tuberculosis testing language; remove option of trial of TNF for consistency for Tremfya; update exclusion list for combination use. Coding reviewed: No changes.
- 06/14/2021 – Select Review: Add quantity limit for new dosage form of Skyrizi. Coding Reviewed: No changes.
- 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

1. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/risk-factors/?CDC_AAref_Val=https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 12, 2024.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 1, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Feuerstein JD, Ho EY, Shmidt E et al. American Gastroenterological Association Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology 2021; 160:2496-2508.
5. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
7. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. *Am J Gastroenterol* 2018; 113:481–517.
8. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019; 80: 1029-72.
9. Rubin DT, Ananthakrishnan AN, Siegel CA et al. American College of Gastroenterology Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413.
10. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.

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

CC-0050 Monoclonal Antibodies to Interleukin-23

Commercial Medical Benefit

Ulcerative Colitis		
Effective Date	**Preferred Agents**	**Non-Preferred Agents**
10/01/2024	Avsola Remicade Infliximab Unbranded Entyvio Stelara IV Skyrizi IV	Omvoh
12/01/2024	Avsola Remicade Infliximab Unbranded Entyvio Stelara IV Skyrizi IV Tremfya IV	Omvoh

Crohn's Disease		
Effective Date	**Preferred Agents**	**Non-Preferred Agents**
3/3/2025	Avsola Remicade Infliximab Unbranded Entyvio Stelara IV Skyrizi IV	Omvoh
7/1/2025	Avsola Remicade Infliximab Unbranded Entyvio Selarsdi IV Stelara IV Skyrizi IV	Omvoh