Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Monoclonal Antibodies to Interleukin-23 [Ilumya® (tildrakizumab-asmn), Omvoh® (mirikizumab-mrkz), Skyrizi® (risankizumab-rzaa), Tremfya® (guselkumab)]	**MP-RX-FP-61-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023** **Last Review Date:** **7/22/2026**	**7/22/2026** **Frequently Revision:** **Annual**

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

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. Agents addressed in this clinical criteria document include:

- Ilumya® (tildrakizumab-asmn)
- Omvoh® (mirikizumab-mrkz)
- Skyrizi® IV (risankizumab-rzaa)
- Tremfya® IV (guselkumab)

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

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guselkumab and risankizumab for psoriatic arthritis.

Crohn's Disease: The American College of Gastroenterology Clinical Guidelines recommend TNFi +/- immunomodulator, vedolizumab, ustekinumab, risankizumab, guselkumab, and mirikizumab for induction and maintenance of remission for moderately to severely active CD. The American Gastrointestinal Association guidelines were published prior to FDA approval of risankizumab, guselkumab, and mirikizumab for CD. The AGA guidelines recommend or suggest TNFi, ustekinumab, or vedolizumab for induction and maintenance of remission. Among the biologics, infliximab, adalimumab, ustekinumab, or vedolizumab are recommended or suggested over certolizumab for induction of remission in individuals who are naïve to biologics. 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).

Ulcerative Colitis: Both the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) Guidelines recommend or suggest TNFi, ozanimod, etrasimod, ustekinumab, guselkumab, mirikizumab, risankizumab, tofacitinib, upadacitinib, and vedolizumab for induction and maintenance of remission for patients with moderately to severely active UC. The AGA Guidelines provide recommendations for the positioning of advanced therapies. The AGA suggests using a higher efficacy medication (infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, guselkumab) or intermediate efficacy medication (golimumab, ustekinumab, tofacitinib, mirikizumab) medication rather than a lower efficacy medication (adalimumab) in individuals who are naïve to advanced therapies. For individuals who have previously been exposed to one or more advanced therapies, particularly TNFi, AGA suggests using a higher efficacy medication (tofacitinib, upadacitinib, ustekinumab) or an intermediate efficacy medication (mirikizumab, risankizumab, guselkumab) rather than a lower efficacy medication (adalimumab, vedolizumab, ozanimod, etrasimod).

Approved Indications

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

A. Plaque psoriasis (Ilumya, Tremfya, and Skyrizi)
B. Psoriatic Arthritis (Tremfya and Skyrizi)
C. Crohn's Disease (Skyrizi, Omvoh, Tremfya)
D. Ulcerative Colitis (Skyrizi, Tremfya, Omvoh)

Other Uses

A. None.

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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.

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); **AND**
   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. Documentation that the patient has been receiving and is maintained on a stable dose of Ilumya; **AND**
ii. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

C. Authorization Duration

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

D. 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:

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A. 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**
B. When the above criteria are not met and for all other indications.

Mirikizumab-mrkz (Omvoh®)

A. Criteria For Initial Approval *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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;

   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.

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;

   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.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Mirikizumab-mrkz (Omvoh®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following information is provided:
   A. Documentation that the patient has been receiving and is maintained on a stable dose of Omvoh; **AND**

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B. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

C. Authorization Duration

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

D. Conditions Not Covered

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

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. When the above criteria are not met and for all other indications.

Risankizumab-rzaa (Skyrizi IV®)

A. Criteria for Initial Approval *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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, 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;

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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, 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. Individual is 18 years of age or older with moderate to severe CD;

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;

      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.

B. Criteria for Continuation of Therapy

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

C. Authorization Duration

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

D. 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:

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A. 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**

B. When the above criteria are not met and for all other indications.

Guselkumab (Tremfya® IV)

A. Criteria for Initial Approval *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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 6 years of age or older weighing at least 40 kg 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;

OR

ii. Psoriatic arthritis (PsA) when each of the following criteria are met:

A. Individual is 6 years of age or older weighing at least 40 kg 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)]; **OR**

C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

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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;

   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

OR

iv. Crohn's Disease (CD) when each of the following criteria are met:
   A. For individuals requesting intravenous or subcutaneous induction doses:
      1. Individual is 18 years of age or older with moderate to severe CD;

   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 or subcutaneous induction doses with Tremfya and will be using subcutaneous Tremfya for maintenance therapy

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. Authorization Duration

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

D. 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 topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, or any of the following biologic immunomodulators: TNF antagonists, other IL-23

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inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**

B. When the above criteria are not met and for all other indications.

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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	Recommended Dosing Schedule
Ilumya (tildrakizumab-asmn) 100 mg/mL	1 prefilled syringe per 84 days (12 weeks)	• 100 mg at weeks 0, 4, and every 12 weeks thereafter
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.		

Omvoh® (Mirikizumab-mrkz) Quantity Limit

Drug	Limit	Recommended Dosing Schedule
Omvoh (mirikizumab-mrkz) 100 mg/mL prefilled pen/syringe	2 pens/syringes per 28 days (4 weeks)	*Ulcerative Colitis* • Induction dosage: 300 mg administered by intravenous infusion at weeks 0, 4 and 8. • Maintenance dosage: 200 mg administered by subcutaneous injection (2 injections of 100 mg each) at Week 12, and every 4 weeks thereafter. *Chrohn's Disease* • Induction dosage: 900 mg administered by intravenous infusion at weeks 0, 4 and 8. • Maintenance dosage: 300 mg administered by subcutaneous injection (given as two consecutive
Omvoh (mirikizumab-mrkz) 200 mg/2 mL prefilled pen/syringe	1 pen/syringe 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 (20mg/mL) single-dose vial	9 vials total to last 12 weeks; one time fill	

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		injections of 100 mg and 200 mg in any order) at Week 12, and every 4 weeks thereafter.

Exceptions

- Patients should be evaluated for tuberculosis (TB) infection prior to initiating treatment with Omvoh.
- Liver enzymes and bilirubin levels should be monitored at baseline and for at least 24 weeks of treatment.
- Complete all age-appropriate vaccinations according to current immunization guidelines (avoid live vaccines).

Skyrizi® IV (risankizumab-rzaa) Quantity Limit

Drug	Limit	Recommended Dosing Schedule
Skyrizi (risankizumab-rzaa) 90 mg/mL syringe^	2 prefilled syringes per 56 days (8 weeks)	*Ulcerative Colitis* • Induction dosage: 1,200 mg administered by intravenous infusion over at least two hours at Week 0, Week 4, and Week 8. • Maintenance dosage: 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter. Use the lowest effective dosage to maintain therapeutic response. *Chrohn's Disease* • Induction dosage: 600 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8. • Maintenance dosage: 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter. Use the lowest effective dosage to maintain therapeutic response. *Plaque Psoriasis and Psoriatic Arthritis:* • 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter. • In patients with psoriatic arthritis SKYRIZI can be administered alone or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs).
Skyrizi (risankizumab-rzaa) 180 mg/ 1.2 mL syringe^	1 prefilled syringe 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; one time fill	

Exceptions

- Liver enzymes and bilirubin levels should be monitored at baseline and, during induction, up to at least 12 weeks of treatment.
- 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 of the 90 mg/mL prefilled syringes OR up to two of the 180 mg/mL prefilled syringes per 56

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days (8 weeks) may be approved if the following criteria are met:

- Information has been provided for the clinical necessity of the prefilled syringe and why the individual is unable to use the 360 mg prefilled cartridge with on-body injector.

Tremfya® IV (guselkumab) Quantity Limit

Drug	Limit	Recommended Dosing Schedule
Tremfya (guselkumab) 100 mg/mL pen/syringe*	1 prefilled pen/syringe per 56 days (8 weeks)	*Ulcerative Colitis and Chrohn's Disease* • Induction dosage: 200 mg administered by intravenous infusion over at least one hour at Week 0, Week 4, and Week 8 or 400 mg administered by subcutaneous injection at Week 0, Week 4, and Week 8. • Maintenance dosage: 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response. *Psoriatic Arthritis* • 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter. Tremfya can be used alone or in combination with a conventional DMARD (e.g., methotrexate). *Plaque Psoriasis* • 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter.
Tremfya (guselkumab) 200 mg/2 mL pen/syringe^	1 pen/syringe per 28 days (4 weeks)	
Tremfya (guselkumab) Induction Pack for Ulcerative Colitis or Crohn's Disease 200 mg/2 mL pen^	3 packs total; one time supply	
Tremfya (guselkumab) 200 mg/20 mL single-dose vial	3 vials total to last 12 weeks; one time fill	

Exceptions

- For the treatment of Crohn's disease or ulcerative colitis, liver enzymes and bilirubin levels should be monitored at baseline, for at least 16 weeks of treatment, and periodically.
- 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.
- Initiation of therapy for Ulcerative colitis or Crohn's Disease: May approve 3 Induction Packs OR up to 6 total (3 additional) pens/syringes (200mg/2mL) in the first 8 weeks of treatment; to be administered as one induction pack OR 2 (two) pens/syringes (200mg/2mL) at week 0, week 4, and week 8.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Monoclonal Antibodies to Interleukin-23 [Ilumya® (tildrakizumab-asmn), Omvoh® (mirikizumab-mrkz), Skyrizi® (risankizumab-rzaa), Tremfya® (guselkumab)]	**MP-RX-FP-61-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023** **Last Review Date:** **7/22/2026**	**7/22/2026** **Frequently Revision:** **Annual**

Codes Information:

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.

ICD-10 Diagnostic Codes:

Codes	Description
K50.0-K50.019	Crohn's disease of small intestine (Skyrizi, Tremfya, Omvoh)
K50.1-K50.119	Crohn's disease of large intestine (Skyrizi, Tremfya, Omvoh)
K50.8-K50.819	Crohn's disease of both small and large intestine (Skyrizi, Tremfya, Omvoh)
K50.9-K50.919	Crohn's disease, unspecified (Skyrizi, Tremfya, Omvoh)
K51.00-K51.919	Ulcerative Colitis (Skyrizi, Tremfya, Omvoh)
L40.0	Psoriasis 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	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)

HCPCS Codes:

Codes	Description
C9399	Unclassified drugs or biologicals [when specified as Skyrizi (risankizumab-rzaa) subcutaneous]
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]
J3590	Unclassified biologics [when specified as Skyrizi (risankizumab-rzaa) subcutaneous]

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Reference Information:

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7. 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.
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13. 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.
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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.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated may not approve criteria; remove infection, tuberculosis testing, and phototherapy combination exclusions as applicable. Removed prerequisite conventional therapy requirements for CD and UC; updated Tremfya clinical criteria with new pediatric indications; clarify phototherapy exclusion applies to psoriasis and psoriatic arthritis; added dosage forms and quantity limit for Skyrizi, Omvoh, and Tremfya; update Tremfya quantity limit for induction pack; clarify quantity limits as one time fill as applicable. Coding Reviewed: Added HCPCS NOC C9399 and J3590 for Skyrizi subcutaneous. Updated reference information and incorporated new policy template.	7/13/2026	7/22/2026
Annual Review	Added Omvoh medical policy (reviewed 12/23/2024) to Monoclonal Antibodies to Interleukin-23 Medical Policy. Added to the approved indication section: Crohn's Disease (Tremfya, Omvoh) and Ulcerative Colitis (Skyrizi). Updated Tremfya and Omvoh clinical criteria with new indications for Crohn's disease. Changed Criteria of Continuation of Therapy section of Skyrizi: "Individual is 18 years of age or older with moderate to severe UC" to "Individual has been receiving and is maintained on a stable dose of Skyrizi". Added quantity limit for new strength, increased quantity limit for vial and added recommended dosing schedule of Omvoh based on the indication for Crohn's disease. Added to Skyrizi and Tremfya (Limits or Restriction section): Liver enzymes and bilirubin levels should be monitored. Coding Reviewed: Added Tremfya and Omvoh for Chron's disease indication in parentheses next to diagnosis descriptions. Update wording and formatting.	8/25/2025	9/8/2025
Annual Review	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	2/24/2025	3/6/2025

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	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.		
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023