Washington State Health Care Authority

Cytokine and CAM Antagonists: IL-12/IL-23 Inhibitors

Medical policy no. **.**.**-* Effective Date: Month, 1, Year

Related medical policies:

Policy Name
66.20.00.AA TNF Inhibitors
66.27.00.AH JAK Inhibitors
66.27.00.AG T-Lymphocyte Inhibitor
66.27.00.AE IL-17 Inhibitors

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
Guselkumab (Tremfya) Risankizumab (Skyrizi) Tildrakizumab (Ilumya) Ustekinumab (Stelara)	**IL-12 and 23 Inhibitors – guselkumab, Risankizumab, tildrakizumab, ustekinumab** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If not all criteria are met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial or reauthorization duration. Patients new to Apple Health or new to an MCO who are requesting regimens for continuation of therapy are reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
Crohn's Disease Risankizumab (Skyrizi) Ustekinumab (Stelara)	Risankizumab (Skyrizi) or ustekinumab (Stelara) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with a gastroenterologist; **AND**

	3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate to severe Crohn's disease (CD); **AND** a. Treatment with conventional therapy has been ineffective, contraindicated, or not tolerated. Conventional therapy is defined as: i. Oral corticosteroids (e.g., prednisone, methylprednisolone) used short-term to induce remission or alleviate signs/symptoms of disease flare; **AND** ii. At least one immunomodulatory agent (e.g., methotrexate, azathioprine, 6-mercaptopurine) [minimum trial of 12 weeks]; **OR** b. Documentation of high-risk disease (e.g., symptoms despite conventional therapy, obstruction, abscess, stricture, phlegmon, fistulas, resection, extensive bowel involvement, early age of onset, growth retardation, Crohn's Disease Activity Index (CDAI) > 450, Harvey-Bradshaw index > 7); **AND** 5. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Risankizumab (Skyrizi) or ustekinumab (Stelara) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in endoscopic activity, taper or discontinuation of corticosteroids, reduction in number of liquid stools, decrease in presence and severity of abdominal pain, decrease in CDAI, decrease in Harvey-Bradshaw index). If ALL criteria are met, the request will be authorized for **12 months.**
Plaque psoriasis Guselkumab (Tremfya) Risankizumaab (Skyrizi) Tildrakizumab (Ilumya) Ustekinumab (Stelara)	Guselkumab (Tremfya), risankizumab (Skyrizi), tildrakizumab (Ilumya), or ustekinumab (Stelara) may be approved when all the following documented criteria are met: 1. Patient meets the appropriate age limit for the requested product: a. For ustekinumab, 6 years of age or older; **OR** b. For guselkumab, Risankizumab and tildrakizumab, 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a dermatologist; **AND**

	3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate to severe plaque psoriasis; **AND** 5. For ustekinumab, documentation of current weight is provided; **AND** 6. Presence of ongoing disease for greater than 6 months; **AND** 7. The patient meets one of the following: a. Disease affects at least 10% body surface area; **OR** b. Disease affects the face, ears, hands, feet, or genitalia; **AND** 8. Baseline assessments are included (e.g., body surface area (BSA), Psoriasis Are and Severity Index (PSAI), Psoriasis Physician's Global Assessment (PGA), itch numeric rating scale, etc.); **AND** 9. History of failure, contraindication, or intolerance to one of the following: a. Phototherapy (UVB or PUVA) [minimum trial of 12 weeks]; **OR** b. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, cyclosporine, acitretin, azathioprine, etc.) [minimum trial of 12 weeks]; **AND** 10. Patient meets one of the following: a. For pediatric ustekinumab requests: Treatment with etanercept has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]; **OR** b. For adult requests: Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Guselkumag (Tremfya), risankizumab (Skyrizi), tildrakizumab (Ilumya or ustekinumab (Stelara) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in BSA, PSAI, Psoriasis PGA, itch numeric rating scale). If ALL criteria are met, the request will be authorized for **12 months.**
Psoriatic arthritis Guselkumab (Tremfya)	Guselkumab (Tremfya), risankizumab (Skyrizi), or ustekinumab (Stelara) may be approved when all the following documented criteria are met:

Risankizumaab (Skyrizi) Ustekinumab (Stelara)	1. Patient meets the appropriate age limit for the requested product: a. For ustekinumab, 6 years of age or older; **OR** b. For gueselkumab and risankizumab, 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a dermatologist or rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Psoriatic Arthritis (PsA); **AND** 5. For ustekinumab, documentation of current weight is provided; **AND** 6. Patient meets one of the following: a. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, cyclosporine) have been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]; **OR** b. Presence of active, severe disease as indicated by provider assessment and the presence of at least ONE of the following: i. Erosive disease ii. Elevated C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) iii. Long-term damage interfering with function (e.g., joint deformities, vision loss) iv. Major impairment of quality of life due to high disease activity at many sites (including dactylitis, enthesitis) or functionally limiting arthritis at a few sites; **AND** 7. For adult requests, treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Guselkumab (Tremfya), risankizumab (Skyrizi), or ustekinumab (Stelara) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.**

Ulcerative Colitis Ustekinumab (Stelara)	Ustekinumab (Stelara) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** a. Documentation of the member's current weight; **AND** 2. Prescribed by, or in consultation with a gastroenterologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate-to-severe Ulcerative Colitis (UC); **AND** 5. Baseline assessments are included (e.g., stool frequency, endoscopy results, presence of rectal bleeding, disease activity scoring tool); **AND** 6. Treatment with conventional therapy (e.g., systemic corticosteroids, azathioprine, mesalamine, sulfasalazine) has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]; **AND** 7. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Ustekinumab (Stelara) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decreased stool frequency, decreased rectal bleeding, improvement in endoscopic activity, tapering or discontinuation of corticosteroid therapy, or improvement on a disease activity scoring tool). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
Ilumya	Plaque psoriasis	100 mg subQ at weeks 0, 4, and then every 12 weeks thereafter	• 100 mg/ml PFS ○ Initial #1: 1 PFS per 28-days for the first month ○ Initial #2: 1 PFS per 84-day supply for months 2-6 ○ Renewal: 1 PFS per 84-day supply for one year

Skyrizi	Plaque psoriasis	150 mg subQ at week 0, 4, and then every 12 weeks thereafter	• 75 mg/0.83mL PFS (#2 per pack): ○ Initial #1: 2 PFS (1 kit) per 28-days for the first month ○ Initial #2: 2 PFS (1 kit) per 84-day supply for months 2-6 ○ Renewal: 2 PFS (1 kit) per 84-day supply for one year • 150 mg/ml PFS or Pen: ○ Initial #1: 1 PFS or pen per 28-days for the first month ○ Initial #2: 1 PFS or pen per 84-day supply for months 2-6 ○ Renewal 1 PFS or pen per 84-day supply for one year
	Psoriatic arthritis		
	Crohn's disease	Induction: 600 mg IV infusion at week 0, 4, and 8 Maintenance: 180 mg or 360 mg subQ at week 12, and every 8 weeks thereafter	• 600 mg/10mL vial ○ Initial #1: 1 vial per 28-days for the first month ○ Initial #2: 1 vial per 28-days for months 2-3 • 360 mg/2.3 ml cartridge (kit) ○ Initial PA: 1 cartridge (kit) (360mg/2.3mL) per 56-day supply for six months ○ Renewal: 1 cartridge (kit) (360mg/2.3mL) per 56-day supply for one year • 180 mg/1.2mL cartridge (kit) ○ Initial PA: 1 cartridge (kit) (180mg/1.2mL) per 56-day supply for six months ○ Renewal: 1 cartridge (kit) (180 mg/1.2mL) per 56-day supply for one year
Stelara	Plaque psoriasis	100 kg or less: 45 mg subQ initially and 4 weeks later, followed by 45 mg every 12 weeks Greater than 100 kg: 90 mg subQ initially and 4 weeks later, followed by 90 mg every 12 weeks	• 45mg/0.5mL PFS (#1 per box) ○ Plaque psoriasis (adults ≤ 100 kg) or Psoriatic arthritis ▪ Initial PA #1: 1 PFS or SDV (45mg/0.5mL) per 28 day supply for one month ▪ Initial PA #2: 1 PFS or SDV (45mg/0.5mL) per 84 day supply for months 2-6 ▪ Renewal: 1 PFS or SDV (45mg/0.5mL) per 84 day supply for one year
	Psoriatic arthritis	45 mg subQ at weeks 0 and 4, then every 12 weeks	

		Greater than 100 kg: coexistent moderate to severe plaque psoriasis, 90 mg subQ at weeks 0 and 4, then every 12 weeks	○ Pediatric Plaque psoriasis (6-17 years old, and < 60 kg) ▪ Initial PA #1: 1 SDV (45mg/0.5mL) per 28 day supply for one month ▪ Initial PA #2: 1 SDV (45mg/0.5mL) per 84 day supply for months 2-6 ▪ Renewal: 1 SDV (45mg/0.5mL) per 84 day supply for one year ○ Pediatric Plaque psoriasis (6-17 years old, and 60 to 100 kg) ▪ Initial PA #1: 1 PFS or SDV (45mg/0.5mL) per 28 day supply for one month ▪ Initial PA #2: 1 PFS or SDV (45mg/0.5mL) per 84 day supply for months 2-6 ▪ Renewal: 1 PFS or SDV (45mg/0.5mL) per 84 day supply for one year • 90mg/mL PFS (#1 per box) ○ Plaque psoriasis (Adults > 100 kg) ▪ Initial PA #1: 1 PFS (90mg/mL) per 28-day supply for one month ▪ Initial PA #2: 1 PFS (90mg/mL) per 84-day supply for months 2-6 ▪ Renewal: 1 PFS (90mg/mL) per 84-day supply for one year ○ Pediatric Plaque psoriasis (6-17 years old, and > 100 kg) ▪ Initial PA #1: 1 PFS (90mg/mL) per 28 day supply for one month ▪ Initial PA #2: 1 PFS 90mg/mL) per 84 day supply for months 2-6 ▪ Renewal: 1 PFS (90mg/mL) per 84 day supply for one year
	Crohn's disease Ulcerative colitis	Induction: 55 kg or less: 260 mg IV as a single dose	• 130 mg/26mL vial ○ Induction 55 kg or less: 2 vials ○ Induction 55 kg to 85 g: 3 vials

		55 kg to 85 kg: 390 mg IV as a single dose Greater than 85 kg: 520 mg IV as a single dose Maintenance: 90 mg subQ every 8 weeks beginning 8 weeks after induction	○ Induction greater than 85 kg: 4 vials • 90 mg/mL PFS ○ Initial PA: 1 PFS (90mg/mL) per 56-day supply for six months ○ Renewal: 1 PFS (90mg/mL) per 56-day supply for one year
Tremfya	Plaque psoriasis	100 mg subQ at week 0, week 4, then every 8 weeks thereafter	• 100 mg/mL one-press autoinjector or PFS (#1 per box) ○ Initial PA #1: 1 autoinjector or PFS per 28 days for the first month ○ Initial PA #2: 1 autoinjector or PFS per 56 days for months 2-6 ○ Renewal PA: #1 autoinjector or PFS per 56 days for one year
	Psoriatic arthritis		

Coding:

HCPCS Code	Description
J1628	Injection, guselkumab, 1 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J3245	Injection, tildrakizumab, loading: 100 billable units (100 mg) at weeks 0 and 4, maintenance: 100 billable units (100 mg) every 12 weeks
J3357	Ustekinumab, for subcutaneous injection, 1 mg

Background:

Crohn's Disease

Therapeutic recommendations for patients with Crohn's disease (CD) are established based upon disease location, disease severity, disease associated complications, and future disease prognosis. The goals of therapy are to induce remission, prevent relapse, and prevent occurrence of disease complications, such as stricture and fistula. According to the 2018 American College of Gastroenterology (ACG) guidelines, for patients with moderate to severe disease and those with moderate to high-risk disease treatment with oral corticosteroids used short term to induce remission is recommended (strong recommendation, moderate level of evidence). However, it is noted that one in five patients will become steroid refractory which is thought to be the result of unreliable efficacy in healing of the mucosa associated with steroids (weak recommendation, low level of evidence). Corticosteroids are also implicated in the development of perforating complications (abscess and fistula) and are relatively contraindicated in those patients. The 2021 American Gastroenterological Association (AGA) clinical guidelines make similar recommendations and suggest the use of corticosteroids in adult outpatients with moderate to severe CD over no treatment for induction of remission (conditional recommendation, moderate level of evidence). In patients with moderate to severe CD who remain symptomatic despite current or prior corticosteroid therapy, 2018 ACG guidelines recommend immunomodulators such as azathioprine, 6-mercaptopurine (strong recommendation, moderate level of evidence), and methotrexate (conditional recommendation, low level of evidence) to be effective for maintenance of remission. Due to slow time to clinical response that may not be evident for as long as 12 weeks, these agents are not recommended for short-term induction. The 2021 AGA guidelines make similar suggestions and recommend use of thiopurines over no treatment for the maintenance of remission (conditional recommendation, low level of evidence). The timing of introduction of biologic agents is a matter of debate and more studies are needed to assess stepwise approach versus earlier administration of biologic agents in patients with moderate to severe disease. The 2019 British Society of Gastroenterology guidelines suggest that systemic corticosteroids are still an effective initial therapy for uncomplicated luminal moderate to severe disease, regardless of disease location; however, every effort should be made to limit exposure (strong recommendation, high-quality evidence). In patients with an aggressive disease course, or high risk, poor prognostic factors, early introduction of biologics may be considered (weak recommendation, moderate-quality evidence). High risk features include extensive disease, complex (stricturing or penetrating disease), perianal fistulizing disease, age under 40 years at diagnosis, and the need for steroids to control index flare; however, the predictive power of these features is limited.

Plaque psoriasis

Plaque psoriasis is a common chronic skin disorder typically characterized by erythematous papules and plaques with a silver scale. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines for the management of psoriasis with systemic nonbiologic therapies and for the management and treatment of psoriasis with biologics indicate that the majority of patients are capable of adequately controlling disease solely with topical medications or phototherapy. Phototherapy is recognized as a beneficial therapy for controlled plaque psoriasis and is a cost-effective treatment strategy. Additionally, oral immunomodulatory medications (e.g., methotrexate, cyclosporine, acitretin) are cost-effective therapies with a well-known safety profile for the treatment of plaque psoriasis. For moderate-to-severe disease, where a JAK inhibitor or biologics are warranted, adalimumab (Humira) and etanercept (Enbrel) are one of many options. However, it would not be indicated for mild psoriasis given that patients are better managed from a safety perspective on well-established therapies (e.g., topical agents, phototherapy, conventional DMARDS, apremilast [Otezla]).

Psoriatic arthritis

Psoriatic arthritis is an inflammatory musculoskeletal disease associated with psoriasis that was initially considered a variant of rheumatoid arthritis but has emerged as a distinct clinical entity. The 2018 American College of Rheumatology/National Psoriasis Foundation Guideline (ACR) for psoriatic arthritis make a conditional recommendation for starting a TNF inhibitor over an oral small molecule (OSM) as a first-line option

for patients who are treatment-naïve with active psoriatic arthritis. This recommendation is based on low- to very-low quality of evidence. Many of the studies in which greater benefit was seen in terms of disease severity or radiographic progression compared methotrexate to TNF inhibitors, however, most patients included in these groups were not truly treatment naïve to OSM medications. Guidelines note that OSM can be used first-line in naïve patients who do not have severe PsA, severe PsO, prefers oral therapy, or has contraindications to TNF inhibitors.

Ulcerative Colitis

The 2019 American College of Gastroenterology (ACG) clinical guideline on the management of ulcerative colitis in adults recommend oral systemic corticosteroids for induction of remission in moderate to severe disease (strong recommendation, moderate quality of evidence). TNF inhibitors (adalimumab, golimumab, and infliximab), vedolizumab (Entyvio), and tofacitinib (Xeljanz) are also recommended for induction of remission (strong recommendation, moderate quality of evidence). For maintenance of remission, thiopurines are recommended if remission was achieved after corticosteroid induction (conditional recommendation, low quality of evidence). The guidelines note a systematic review of 1,632 patients with ulcerative colitis demonstrated that azathioprine and mercaptopurine had a 76% mean efficacy in maintaining remission. If remission was achieved with anti-TNF therapy, vedolizumab (Entyvio), or tofacitinib (Xeljanz), clinical guidelines support continuing with the same agent to maintain remission (strong recommendation, moderate quality of evidence). The 2020 American Gastroenterology Association (AGA) guidelines make similar recommendations. Additionally, AGA recommends early use of biologic agents, rather than gradual step up after failure of 5-ASA in moderate to severe disease at high risk for colectomy. However, overall quality of evidence supporting this recommendation was rated as very low. Guidelines also note that for patients with less severe disease, 5-ASA therapy may still be a reasonable choice of therapy to start with. For maintenance of remission, AGA makes no recommendation in favor of, or against, using biologic monotherapy, rather than thiopurine monotherapy due to absence of evidence.

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History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Pending Approval (draft/unpublished version) -Updated clinical criteria for indication A to require Lab A. -Added indication for X. -Added new products in class which include Drug A and Drug B. -Updating dosing for Drug A. -Updating language at header note to include “If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.”
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Approved by HCA. Updated dosing limits for expanded indication for drug X.
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Approved by DUR Board.