Department:	Pharmacy Management	**Original Approval:**	03/12/2025
Policy No:	PM601	**Last Approval:**	03/06/2026
Policy Title:	IL-12/IL-23 Inhibitor Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Dosing and duration requested -Weight -Age -Medication list (current and past) to include start and end dates of previous trials for all conventional synthetic disease-modifying anti-rheumatic drugs (DMARD)/other small molecule drugs and biologic drugs -Prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, neurologist, oncologist, hematologist or other specialist as indicated.

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.

Indications/Criteria

Medicaid Members	**The medications listed above are included in WA HCA's Single Preferred Drug List with criteria from WA HCA Cytokine & CAM Antagonists Medical policy no. 66.27.00.AD** ***Preferred Products: Adalimumab biosimilars; Ustekinumab biosimilars; Xeljanz IR***
Individual & Family (Cascade Select) Members	***Preferred Products: Tremfya, Skyrizi Intravenous, Omvoh, Stelara/ustekinumab Intravenous, Yesintek Intravenous, Selarsdi Intravenous*** ***Non-Preferred Products: Imuldosa intravenous, Wezlana intravenous, Otulfi intravenous, Steqeyma intravenous, Pyzchiva intravenous***
Medicare Members	***Medicare Criteria is only applicable to the preferred and non-preferred products listed below. For all other drugs, refer to MCG. All other drugs do not require trial of a preferred product.*** ***Preferred Products: Tremfya, Skyrizi Intravenous, Omvoh, Stelara/ustekinumab Intravenous, Yesintek Intravenous, Selarsdi Intravenous*** ***Non-Preferred Products: Imuldosa intravenous, Wezlana intravenous, Otulfi intravenous, Steqeyma intravenous, Pyzchiva intravenous***

Medicaid Criteria for Risankizumab, Ustekinumab, Guselkumab, Mirikuzumab (taken from HCA Medical Policy No. 66.27.00.AD)

Clinical Criteria	
Crohn's Disease Guselkumab (Tremfya)	Preferred ustekinumab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND**

Mirikuzumab (Omvoh) Risankizumab (Skyrizi) Ustekinumab (Stelara) Ustekinumab biosimilars	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, unless all are 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) For guselkumab (Tremfya), Mirikuzumab (Omvoh), or risankizumab (Skyrizi) may be approved when all the following documented criteria are met:: Treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars and ustekinumab biosimilars) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. 5. Criteria 1-4 above is met; **AND** 6. Treatment with two preferred Cytokine and CAM medications (adalimumab biosimilars and ustekinumab biosimilars) has each been ineffective, unless all are contraindicated or not tolerated [minimum trial of 12 weeks]. Note: Please see **Appendix A** for the list of preferred biosimilars. Non-preferred ustekinumab biosimilars and brand ustekinumab (Stelara) may be approved when all the following criteria are met: 7. Criteria 1-4 above is met; AND 8. Patient meets both of the following: a. Trial of one preferred adalimumab biosimilar; **AND** Note: Please see **Appendix A** for the list of preferred biosimilars.

	b. Trial of 5 ustekinumab biosimilars. Note: See Dosage and Quantity for list of all ustekinumab biosimilars. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Guselkumab (Tremfya), Mirikuzumab (Omvoh), risankizumab (Skyrizi), ustekinumab (Stelara) or ustekinumab biosimilars 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.**
Ulcerative Colitis Guselkumab (Tremfya) Mirikizumab (Omvoh) Risankizumab (Skyrizi) Ustekinumab (Stelara) ustekinumab biosimilars	Preferred ustekinumab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Documentation of the patient's current weight; **AND** 3. Prescribed by, or in consultation with a gastroenterologist; **AND** 4. Not used in combination with another Cytokine and CAM medication; **AND** 5. Diagnosis of moderate-to-severe Ulcerative Colitis (UC); **AND** 6. Baseline assessments are included (e.g., stool frequency, endoscopy results, presence of rectal bleeding, disease activity scoring tool); **AND** 7. Treatment with conventional therapy (e.g., systemic corticosteroids, azathioprine, mesalamine, sulfasalazine) has been ineffective, unless all are contraindicated or not tolerated [minimum trial of 12 weeks]; **AND** Guselkumab (Tremfya), Mirikuzumab (Omvoh), or risankizumab (Skyrizi) may be approved when all of the following documented criteria are met: 8. Criteria 1 above is met; **AND**

	9. Criteria 3-7 above is met; **AND** 10. Treatment with two preferred Cytokine and CAM medications (i.e., adalimumab biosimilars, ustekinumab biosimilars, or Xeljanz IR) has each been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. Non-preferred ustekinumab biosimilars and brand ustekinumab (Stelara) may be approved when all the following criteria are met: 11. Criteria 1-7 above is met; **AND** 12. Patient meets all of the following: a. Trial of one preferred adalimumab biosimilar; **AND** Note: Please see **Appendix A** for the list of preferred biosimilars. b. Trial of Xeljanz IR; **AND** c. Trial of 5 ustekinumab biosimilars. Note: See Dosage and Quantity for list of all ustekinumab biosimilars. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Guselkumab (Tremfya), mirikizumab (Omvoh),ustekinumab (Stelara) or ustekinumab biosimilars 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
Omvoh	Ulcerative colitis	Induction: 300 mg IV at week 0, week 4, and week 8	• Omvoh 300 mg/10 mL vial

		Maintenance: 200 mg subQ at week 12 and every 4 weeks thereafter	○ Initial #1: 1 vial per 28-days for the first month ○ Initial #2: 1 vial per 28-days for months 2-3 • Omvoh PFS or Pen 100 mg/1 mL ○ Initial: 2 PFS or pens per 28-days ○ Renewal: 2 PFS or pens per 28-days
Skyrizi	Crohn's disease	Induction: 600 mg IV infusion at week 0, 4, and 8	• 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
Stelara	Crohn's disease Ulcerative colitis	Induction: 55 kg or less: 260 mg IV as a single dose 55 kg to 85 kg: 390 mg IV as a single dose Greater than 85 kg: 520 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 ○ Induction greater than 85 kg: 4 vials
Tremfya	Ulcerative colitis	Ulcerative Colitis: Induction: 200 mg IV at week 0, 4, and 8	• Ulcerative Colitis ○ 10 mg/mL intravenous solution ▪ Induction Initial PA #1: 200 mg at weeks 0, 4, and 8, total 600 mg.
Ustekinumab biosimilars			
Ustekinumab-aauz (Otulfi)	Crohn's disease Ulcerative Colitis	Induction: 55 kg or less: 260 mg IV as a single dose 55 kg to 85 kg: 390 mg IV as a single dose Greater than 85 kg: 520 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 ○ Induction greater than 85 kg: 4 vials
Ustekinumab-aekn (Selarsdi)	Crohn's disease Ulcerative Colitis	Induction: 55 kg or less: 260 mg IV as a single dose 55 kg to 85 kg: 390 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 ○ Induction greater than 85 kg: 4 vials

		Greater than 85 kg: 520 mg IV as a single dose	
Ustekinumab -auub (Wezlana)	Crohn's disease Ulcerative Colitis	Induction: 55 kg or less: 260 mg IV as a single dose 55 kg to 85 kg: 390 mg IV as a single dose Greater than 85 kg: 520 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 ○ Induction greater than 85 kg: 4 vials
Ustekinumab -kfce (Yesintek)	Crohn's disease Ulcerative Colitis	Induction: 55 kg or less: 260 mg IV as a single dose 55 kg to 85 kg: 390 mg IV as a single dose Greater than 85 kg: 520 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 ○ Induction greater than 85 kg: 4 vials
Ustekinumab -stba (Steqeyma)	Crohn's disease Ulcerative Colitis	Induction: 55 kg or less: 260 mg IV as a single dose 55 kg to 85 kg: 390 mg IV as a single dose Greater than 85 kg: 520 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 ○ Induction greater than 85 kg: 4 vials
Ustekinumab-ttwe (Pyzchiva)	Crohn's disease Ulcerative Colitis	Induction: 55 kg or less: 260 mg IV as a single dose 55 kg to 85 kg: 390 mg IV as a single dose Greater than 85 kg: 520 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 ○ Induction greater than 85 kg: 4 vials

Individual & Family (Cascade Select) Select and Medicare Criteria

Tremfya (Guselkumab) Approved Indications

1. **Ulcerative Colitis.** Approve three doses for induction if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried one systemic therapy; OR

       Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix B for examples of biologics used for ulcerative colitis.
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has pouchitis; AND
       - **b)** Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND

         Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist.

Dosing: Approve 200 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

Omvoh Approved Indications

1. **Ulcerative Colitis.** Approve three doses for induction if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried one systemic therapy; OR

       Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix B for examples of biologics used for ulcerative colitis.

ii. Patient meets BOTH of the following (a and b):
- **a)** Patient has pouchitis; AND
- **b)** Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND

  Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

D) The medication is prescribed by or in consultation with a gastroenterologist.

Dosing: Approve 300 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

Skyrizi (Risankizumab-rzaa) Intravenous Approved Indications

1. **Crohn's Disease**. Approve three doses for induction if the patient meets the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets one of the following (i, ii, iii, or iv):
     - **i.** Patient has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this patient; OR
     - **ii.** Patient has tried one other conventional systemic therapy for Crohn's disease; OR

       Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. A previous trial of a biologic also counts as a trial of one other agent for Crohn's disease.
     - **iii.** Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
     - **iv.** Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist.

   Dosing: Approve 600 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

2. **Ulcerative Colitis.** Approve three doses for induction if the patients meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried one systemic therapy; OR

       Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested

biologic does not count. Refer to Appendix B for examples of biologics used for ulcerative colitis.

ii. Patient meets BOTH of the following (a and b):
- **a)** Patient has pouchitis; AND
- **b)** Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND
  Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

D) The medication is prescribed by or in consultation with a gastroenterologist.

Dosing: Approve 1,200 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

Ustekinumab Intravenous Products Approved Indications (if requesting Imuldosa intravenous, Wezlana intravenous, Otulfi intravenous, Steqeyma intravenous, Pyzchiva intravenous, please also see Recommended Exception Criteria)

1. **Crohn's Disease**. Approve a single dose if the patient meets the following (A, B, C, and D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication will be used as induction therapy; AND
   - **C)** Patient meets one of the following (i, ii, iii, or iv):
     - **i.** Patient has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this patient; OR
     - **ii.** Patient has tried one other conventional systemic therapy for Crohn's disease; OR
       Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. A previous trial of a biologic also counts as a trial of one other agent for Crohn's disease. Refer to Appendix B for examples of biologics used for Crohn's disease.
     - **iii.** Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
     - **iv.** Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist.

   Dosing. Approve ONE of the following weight-based doses (A, B, or C):
   - **A)** ≤ 55 kg (121 lbs): Approve up to 260 mg as an intravenous infusion; OR
   - **B)** > 55 kg but ≤ 85 kg (> 121 lbs but ≤ 187 lbs): Approve up to 390 mg as an intravenous infusion; OR
   - **C)** > 85 kg (> 187 lbs): Approve up to 520 mg as an intravenous infusion.

2. **Ulcerative Colitis.** Approve a single dose if the patient meets the following criteria (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND
B) The medication will be used as induction therapy; AND
C) Patient meets ONE of the following (i or ii):
  i. Patient has tried one systemic therapy; OR
  Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, a corticosteroid such as prednisone or methylprednisolone, or janus kinase (JAK) inhibitors. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix B for examples of biologics used for ulcerative colitis.
  ii. Patient meets BOTH of the following (a and b):
    a) Patient has pouchitis; AND
    b) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND
    Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.
D) The medication is prescribed by or in consultation with a gastroenterologist.

Dosing. Approve ONE of the following weight-based doses (A, B, or C):
A) ≤ 55 kg (121 lbs): Approve up to 260 mg as an intravenous infusion; OR
B) > 55 kg but ≤ 85 kg (> 121 lbs but ≤ 187 lbs): Approve up to 390 mg as an intravenous infusion; OR
C) > 85 kg (> 187 lbs): Approve up to 520 mg as an intravenous infusion.

Recommended Exception Criteria for Individual & Family (Cascade Select) Select and Medicare

Non-Preferred Products	Exception Criteria
Imuldosa intravenous, Wezlana intravenous, Otulfi intravenous, Steqeyma intravenous, Pyzchiva intravenous	**1.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the Individual & Family (Cascade Select) Select and Medicare Criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets BOTH of the following (a and b): **a)** Patient has tried TWO of Stelara/ustekinumab, Yesintek, or Selarsdi intravenous products **[documentation required]**; AND **b)** Patient cannot continue to use the Preferred medications due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which,

	according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**; OR **ii.** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.

Special Considerations

None.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Cascade Select	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

Citations & References

CFR	42 CFR § 438.210	
WAC	WAC 284-43-2050	
RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 11.3: Medical Necessity Determination
	☒ **AHE**	IMC Section 11.3: Medical Necessity Determination
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements

Other Requirements	
NCQA Elements	
References	1. Adalimumab (Humira) [Prescribing Information] North Chicago, IL; AbbVie Inc., February 2021. 2. Ustekinumab (Stelara) [Prescribing Information] Raritan, NJ; Janssen Biotech, Inc. December 2020. 3. Risankizumab (Skyrizi) [Prescribing Information]. North Chicago, IL; AbbVie. Updated January 2021. 4. Singh S, Fumery M, Sandborn WJ, et al. Systematic review and network meta-analysis: first- and second-line biologic therapies for moderate-severe Crohn's disease. Aliment Pharmacol Ther. 2018;48(4):394-409. doi:10.1111/apt.14852 5. Ma C, Lee JK, Mitra AR, et al. Systematic review with meta-analysis: efficacy and safety of oral Janus kinase inhibitors for inflammatory bowel disease. Aliment Pharmacol Ther. 2019;50(1):5-23. doi:10.1111/apt.15297 6. Nelson SM, Nguyen TM, McDonald JW, et al. Natalizumab for induction of remission in Crohn's disease. Cochrane Database Syst Rev. 2018;8(8):CD006097. Published 2018 Aug 1. doi:10.1002/14651858.CD006097.pub3 7. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113(4):481-517. 8. Lamb, Christopher Andrew et al. “British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults.” Gut vol. 68,Suppl 3 (2019): s1-s106. doi:10.1136/gutjnl-2019-318484 9. UpToDate, Inc. Overview of the management of Crohn disease in children and adolescents. UpToDate [database online]. Waltham, MA. Last updated September 14, 2021. Available at: http://www.uptodate.com/home/index.html. 10. van Rheenen PF, Aloi M, Assa A, et al. The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update [published online ahead of print, 2020 Oct 7]. J Crohns Colitis. 2020;jjaa161. doi:10.1093/ecco-jcc/jjaa161 11. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and

Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022
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37. Vedolizumab (Entyvio) [Prescribing Information] Chuo-ku, Tokyo, Japan; Takeda Inc., Updated March 2020.
38. Ozanimod (Zeposia) [Prescribing Information] New York, NY; Bristol Myers Squibb Inc., Updated May 2021.
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Revision History

Revision Date	Revision Description	Revision Made By
03/11/2025	New Policy	Alan Gabot, PharmD
03/12/2025	Approval	UM Criteria Subcommittee
05/13/2025	Early update. Added Otulfi, Pyzchiva, Selarsdi, Steqeyma, Yesintek, and generic Ustekinumab-ttwe	Alan Gabot, PharmD

	(from Pyzchiva) to the policy. The same criteria apply for all Ustekinumab intravenous products.	
06/18/2025	Early update. For Medicaid, updated preferred language for all medications. Added Crohn's Disease indication for Tremfya	Alan Gabot, PharmD
06/24/2025	Approval	UM Criteria Subcommittee
08/12/2025	Early update. For Medicaid criteria, updated preferred language for ustekinumab biosimilars. For Medicaid, added Skyrizi as a covered medication for ulcerative colitis. For Cascade Select/Medicare criteria, added Imuldosa to the policy. Listed Stelara/ustekinumab, Yesintek, and Selarsdi as preferred products. Imuldosa, Wezlana, Otulfi, Steqeyma, and Pyzchiva were listed as non-preferred products. Made additional criteria for non-preferred products, requiring that the member try two preferred products.	Alan Gabot, PharmD
08/13/2025	Approval	UM Criteria Subcommittee
09/09/2025	Early update. For Non-Preferred Products for Cascade Select and Medicare, criteria related to trying a preferred product were separated for the clinical criteria. This portion of the criteria is now labeled under the "Recommended Exception Criteria".	Alan Gabot, PharmD
03/05/2026	Early update. For Medicaid, added generic adalimumab-bwwd, Hadlima, and Pyzchiva as preferred products. Removed Appendix Table of Preferred Products for Cascade Select/Medicare.	Alan Gabot, PharmD
03/06/2026	Approval	UM Criteria Subcommittee

Appendix A. Preferred Biosimilars for Medicaid

Preferred Adalimumab Biosimilars	Generic adalimumab-aaty, generic adalimumab-adbm, generic adalimumab-adaz, generic adalimumab-bwwd, Hadlima
Preferred Ustekinumab Biosimilars	Pyzchiva, Selarsdi, Steqeyma, Yesintek

Appendix B

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC IV formulation: UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC

APPENDIX B (CONTINUED)

	Mechanism of Action	Examples of Indications*
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.