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

WA.PHAR.49.AD Effective Date: 3/1/2025

Related medical policies:

Policy Number	Policy Name
WA.PHAR.49.AA	Cytokine and CAM Antagonists: Tumor Necrosis Factor (TNF) Inhibitors
WA.PHAR.49.AB	Cytokine and CAM Antagonists: IL-4/IL-13 Inhibitors
WA.PHAR.49.AC	Cytokine and CAM Antagonists: IL-6 Inhibitors
WA.PHR.49.AE	Cytokine and CAM Antagonists: IL-17 Inhibitors
WA.PHAR.49.AF	Cytokine and CAM Antagonists: Oral PDE-4 Inhibitors
WA.PHAR.49.AG	Cytokine and CAM Antagonists: T-Lymphocyte Inhibitors
WA.PHAR.49.AH	Cytokine and CAM Antagonists: Janus Associated Kinase (JAK) Inhibitors
WA.PHAR.49.AI	Cytokine and CAM Antagonists: IL-1 Inhibitors
WA.PHAR.49.AJ	Cytokine and CAM Antagonists: Integrin Receptor Antagonists
WA.PHAR.49.AK	Cytokine and CAM Antagonists: S1-P Receptor Modulator

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 publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit:
https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare_Washington.pdf

Medical necessity

Drug	Medical Necessity
Guselkumab (Tremfya) Mirikizumab (Omvoh) Risankizumab-rzaa (Skyrizi) Tildrakizumab (Ilumya) Ustekinumab (Stelara) <u>Ustekinumab Biosimilars:</u> Ustekinumab-auub (Wezlana) Ustekinumab-kfce (Yesintek) Ustekinumab-stba (Steqeyma)	**IL-12 and 23 Inhibitors – guselkumab, mirikizumab, risankizumab, tildrakizumab, ustekinumab, ustekinumab biosimilars** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Policy: IL-12 and 23 inhibitors

Clinical Criteria	
Crohn's Disease Mirikizumab (Omvoh) Risankizumab (Skyrizi) Ustekinumab (Stelara) Ustekinumab biosimilars	Mirikizumab (Omvoh), risankizumab (Skyrizi), ustekinumab (Stelara), or ustekinumab biosimilars 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, 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); **AND** 5. Treatment with one preferred adalimumab biosimilar has been ineffective, unless all are contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Mirikizumab (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.**
Plaque psoriasis Guselkumab (Tremfya) Risankizumaab (Skyrizi) Tildrakizumab (Ilumya)	Guselkumab (Tremfya), risankizumab (Skyrizi), tildrakizumab (Ilumya), ustekinumab (Stelara), or ustekinumab biosimilars may be approved when all the following documented criteria are met: 1. Patient meets the appropriate age limit for the requested product:

Ustekinumab (Stelara) Ustekinumab biosimilars	a. For ustekinumab or ustekinumab biosimilars, 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 or Ustekinumab biosimilars, 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 Area and Severity Index (PASI), Psoriasis Physician's Global Assessment (PGA), itch numeric rating scale, etc.); **AND** 9. History of failure to one of the following, unless all are contraindicated or not tolerated: 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 or Ustekinumab biosimilar requests: Treatment with etanercept has each been ineffective, unless contraindicated or not tolerated [minimum trial of 12 weeks]; **OR** b. For adult requests: Treatment with one preferred adalimumab biosimilar and etanercept has each been ineffective, unless all are 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), tildrakizumab (Ilumya), 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 BSA, PASI, Psoriasis PGA, itch numeric rating scale). If ALL criteria are met, the request will be authorized for **12 months.**

Psoriatic arthritis Guselkumab (Tremfya) Risankizumaab (Skyrizi) Ustekinumab (Stelara) Ustekinumab biosimilars	Guselkumab (Tremfya), risankizumab (Skyrizi), ustekinumab (Stelara) or ustekinumab biosimilars 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 or Ustekinumab biosimilars, 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 or Ustekinumab biosimilars, 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) has been ineffective, unless all are 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 one preferred adalimumab biosimilar and etanercept has each been ineffective, unless all are 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), 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 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 Guselkumab (Tremfya) Mirikizumab (Omvoh) Ustekinumab (Stelara) ustekinumab biosimilars	Guselkumab (Tremfya), mirikizumab (Omvoh), ustekinumab (Stelara) or ustekinumab biosimilars may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** a. For Ustekinumab or Ustekinumab biosimilars: Documentation of the patient'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, unless all are contraindicated or not tolerated [minimum trial of 12 weeks]; **AND** 7. Treatment with one preferred adalimumab biosimilar each been ineffective, unless all are 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), 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
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

Omvoh	Ulcerative colitis	Induction: 300 mg IV at week 0, week 4, and week 8 Maintenance: 200 mg subQ at week 12 and every 4 weeks thereafter	• Omvoh 300 mg/10 mL vial ○ 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	Plaque psoriasis Psoriatic arthritis	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
	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	• 45mg/0.5mL PFS (#1 per box) ○ Plaque psoriasis (adults ≤ 100 kg) or Psoriatic arthritis

		Greater than 100 kg: 90 mg subQ initially and 4 weeks later, followed by 90 mg every 12 weeks	▪ 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 ○ 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
	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	

			▪ 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 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	• 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 • 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 Psoriatic arthritis Ulcerative colitis	Plaque psoriasis and psoriatic arthritis: 100 mg subQ at week 0, week 4, then every 8 weeks thereafter Ulcerative Colitis: Induction: 200 mg IV at week 0, 4, and 8 Ulcerative Colitis: Maintenance: 100 mg at subQ at week 16 and every 8 weeks thereafter OR 200 mg at week 12 and every 4 weeks thereafter.	• Plaque psoriasis and psoriatic arthritis ○ 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 • Ulcerative Colitis ○ 10 mg/mL intravenous solution ▪ Induction Initial PA #1: 200 mg at weeks 0, 4, and 8, total 600 mg. ○ 100 mg/mL one-press autoinjector or PFS (#1 per box) ▪ Maintenance PA option #1: 1 autoinjector or PFS every 8 weeks starting at week 16. ▪ Maintenance PA option #2: 1 autoinjector every 8 weeks starting at week 12.
Ustekinumab biosimilars			
Ustekinumab -auub (Wezlana)	Plaque psoriasis	100 kg or less: 45 mg subQ initially and 4 weeks later, followed by 45 mg every 12 weeks	• 45mg/0.5mL PFS (#1 per box) ○ Plaque psoriasis (adults ≤ 100 kg) or Psoriatic arthritis

		Greater than 100 kg: 90 mg subQ initially and 4 weeks later, followed by 90 mg every 12 weeks	▪ 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 ○ 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
	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	

			▪ Renewal: 1 PFS (90mg/mL) per 84 day supply for one year
	Crohn's disease	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 Maintenance: 90 mg subQ every 8 weeks beginning 8 weeks after induction	• 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 • 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
Ustekinumab -kfce (Yesintek)	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 ○ 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)
	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	

			○ 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	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 Maintenance: 90 mg subQ every 8 weeks beginning 8 weeks after induction	• 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 • 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
Ustekinumab -stba (Steqeyma)	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 ○ Pediatric Plaque psoriasis (6-17 years old, and < 60 kg)
	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	

			▪ 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	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 Maintenance:	• 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 • 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

		90 mg subQ every 8 weeks beginning 8 weeks after induction	

Coding:

HCPCS Code	Description
J1628	Injection, guselkumab, 1 mg
J2327	Injection, 13isankizumab-rzaa, intravenous, 1 mg
J3245	Injection, tildrakizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous 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.

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
12. Ixekizumab (Taltz) [Prescribing Information]. Indianapolis, IN; Eli Lilly. Updated May 2020.
13. Guselkumab (Tremfya) [Prescribing Information]. Horsham, PA; Janssen. Updated July 2020.
14. Risankizumab (Skyrizi) [Prescribing Information]. North Chicago, IL; AbbVie. Updated March 2020.
15. Ustekinumab (Stelara) [Prescribing Information]. Horsham, PA; Janssen. Updated July 2020.
16. 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(4):1029-1072.
17. Menter A, Gelfand JM, Connor C et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Amer Academy of Dermol 2020;82:1445-86.
18. Sbidian E, Chaimani A, Afach Sivem et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. *Cochrane Database Syst Rev* 2020;1(1):1-602.
19. Singh S, Singh S, Thangaswamy A et al. Efficacy and safety of Risankizumab in moderate to severe psoriasis: A systematic review and meta-analysis*. Dermatol Ther* 2020;e14487.
20. Sawyer LM, Cornic L, Levin LA et al. Long-term efficacy of novel therapies in moderate-to-severe plaque psoriasis: a systematic review and network meta-analysis of PASI response. *J Eur Acad Dermatol Venereol* 2019;33(2):355-366.
21. Lebwohl M, Blauvelt A, Paul C et al. Certolizumab pegol for the treatment of chronic plaque psoriasis: Results through 48 weeks of a phase 3, multicenter, randomized, double-blind, etanercept- and placebo-controlled study (CIMPACT). *Acad Dermatol* 2018;79(2):266-276.
22. Reich K, Armstrong AW, Langley RG et al. Guselkumab versus secukinumab for the treatment of moderate-to-severe psoriasis (ECLIPSE): results from a phase 3, randomised controlled trial. *Lancet* 2019;394(10201):831-839.
23. UpToDate, Inc. Psoriasis: Epidemiology, clinical manifestations, and diagnosis. UpToDate [database online]. Waltham, MA. Last updated December 30, 2019. Available at: http://www.uptodate.com/home/index.html.
24. Stein Gold L, Papp K, Pariser D, et al. Efficacy and safety of apremilast in patients with mild-to-moderate plaque psoriasis: Results of a phase 3, multicenter, randomized, double-blind, placebo-controlled trial. J Am Acad Dermatol. 2022 Jan;86(1):77-85. doi: 10.1016/j.jaad.2021.07.040. Epub 2021 Jul 31. PMID: 34343599.
25. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32.
26. Kingsley GH, Scott DL. Assessing the effectiveness of synthetic and biologic disease-modifying antirheumatic drugs in psoriatic arthritis - a systematic review. Psoriasis (Auckl). 2015;5:71-81.
27. Mease PJ, Gladman DD, Samad AS, et al. Design and rationale of the Study of Etanercept and Methotrexate in Combination or as Monotherapy in Subjects with Psoriatic Arthritis (SEAM-PsA). RMD Open. 2018;4(1):e000606.
28. UpToDate, Inc. Treatment of psoriatic arthritis. UpToDate [database online]. Waltham, MA. Last updated November 20, 2018. Available at: http://www.uptodate.com/home/index.html.
29. Deodhar A, Helliwell PS, Boehncke WH, et al. Guselkumab in patients with active psoriatic arthritis who were biologic-naive or had previously received TNFα inhibitor treatment (DISCOVER-1): a double-blind, randomised, placebo-controlled phase 3 trial [published correction appears in Lancet. 2020 Apr 4;395(10230):1114]. Lancet. 2020;395(10230):1115-1125. doi:10.1016/S0140-6736(20)30265-8
30. Mease PJ, Rahman P, Gottlieb AB, et al. Guselkumab in biologic-naive patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial [published correction appears in Lancet. 2020 Apr 4;395(10230):1114]. Lancet. 2020;395(10230):1126-1136. doi:10.1016/S0140-6736(20)30263-4

31. Kristensen LE, Keiserman M, Papp K,et al. Efficacy and safety of risankizumab for active psoriatic arthritis: 24-week results from the randomised, double-blind, phase 3 KEEPsAKE 1 trial. Ann Rheum Dis. 2022 Feb;81(2):225-231. doi: 10.1136/annrheumdis-2021-221019. Epub 2021 Dec 15. PMID: 34911706; PMCID: PMC8762015
32. Östör A, Van den Bosch F, Papp K, et al. Efficacy and safety of risankizumab for active psoriatic arthritis: 24-week results from the randomised, double-blind, phase 3 KEEPsAKE 2 trial. Ann Rheum Dis. 2021 Nov 23:annrheumdis-2021-221048. doi: 10.1136/annrheumdis-2021-221048. Epub ahead of print. PMID: 34815219.
33. Gossec L, Baraliakos X, Kerschbaumer A, et alEULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 updateAnnals of the Rheumatic Diseases 2020;79:700-712.
34. Ustekinumab (Stelara) [Prescribing Information]. Horsham, PA; Janssen. Updated December 2020.
35. Golimumab (Simponi) [Prescribing Information] Raritan, NJ; Janssen Biotech, Inc. Updated September 2019.
36. Infliximab (Remicade) [Prescribing Information] Raritan, NJ; Janssen Biotech, Inc. Updated May 2020.
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.
39. Tofacitinib (Xeljanz) [Prescribing Information] New York, NY; Pfizer Inc., Updated September 2020.
40. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114(3):384-413.
41. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158(5):1450-1461. doi:10.1053/j.gastro.2020.01.006
42. Sands BE, Peyrin-Biroulet L, Loftus EV Jr, et al. Vedolizumab versus Adalimumab for Moderate-to-Severe Ulcerative Colitis. N Engl J Med. 2019 Sep 26;381(13):1215-1226. doi:10.1056/NEJMoa1905725. PMID: 31553834.
43. Sands BE, Sandborn WJ, Panaccione R, et al. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med. 2019 Sep 26;381(13):1201-1214. doi: 10.1056/NEJMoa1900750. PMID: 31553833.
44. Paschos P, Katsoula A, Salanti G, et al. Systematic review with network meta-analysis: the impact of medical interventions for moderate-to-severe ulcerative colitis on health-related quality of life. Aliment Pharmacol Ther. 2018 Dec;48(11-12):1174-1185. doi: 10.1111/apt.15005. Epub 2018 Oct 30. PMID: 30378141.
45. Trigo-Vicente C, Gimeno-Ballester V, García-López S, et al. Systematic review and network meta-analysis of treatment for moderate-to-severe ulcerative colitis. Int J Clin Pharm. 2018 Dec;40(6):1411-1419. doi: 10.1007/s11096-018-0743-4. Epub 2018 Nov 26. PMID: 30478492.
46. Bonovas S, Lytras T, Nikolopoulos G, et al. Systematic review with network meta-analysis: comparative assessment of tofacitinib and biological therapies for moderate-to-severe ulcerative colitis. Aliment Pharmacol Ther. 2018 Feb;47(4):454-465. doi: 10.1111/apt.14449. Epub 2017 Dec 4. PMID: 29205421.
47. Zeposia (ozanimod) Clinical Summary: TRUENORTH phase 3 trial for Ulcerative Colitis. Bristol Myers Squibb. December 2020.
48. Turner et al. Management of Paediatric Ulcerative Colitis, Part 1: Ambulatory Care—An Evidence-based Guideline From European Crohn's and Colitis Organization and European Society of Paediatric Gastroenterology, Hepatology and Nutrition, Journal of Pediatric Gastroenterology and Nutrition: August 2018.
49. Leu JH, Shiff NJ, Clark M, Bensley K, Lomax KG, Berezny K, Nelson RM, Zhou H, Xu Z. Intravenous Golimumab in Patients with Polyarticular Juvenile Idiopathic Arthritis and Juvenile Psoriatic Arthritis and Subcutaneous Ustekinumab in Patients with Juvenile Psoriatic Arthritis: Extrapolation of Data from Studies in Adults and Adjacent Pediatric Populations. Paediatr Drugs. 2022 Sep 28. doi: 10.1007/s40272-022-00533-y. Epub ahead of print. PMID: 36171515.

History:

Approved Date	Effective Date	Version	Action and Summary of Changes
08.14.2024	04.01.2025	66.27.00.AD-5	- Added language for preferred and non-preferred adalimumab biosimilars - Added new products to the market Steqeyma and Yesintek - Formatting updates
08.14.2024	03.01.2025	66.27.00.AD-4	Approved by DUR Board - Split 66.27.00 policy into different policies -Added new drug indications when applicable -Update language in medical necessity section

Previous policy changes (relevant from Cytokine & CAM Antagonists Policy)	
Date	**Action and Summary of Changes**
10.21.2021	Removed Hyrimoz from the policy and updated the initial dosing for infliximab.
11.30.2020	Removed Preferred/Non-Preferred listing and added link to AHPDL publication
11.12.2020	Added language in clinical policy section for cases which do not meet policy criteria
09.01.2020	Updated wording in clinical criteria for products with only one preferred option.
08.19.2020	Approved by DUR Board
8.20.2020	Update to dosing and limits section for all products and indications
08.12.2020	Updated policy clinical criteria and dosing & quantity limits to include nonradiographic axial spondyloarthritis
06.01.2020	Added new agents to class; updated age limit for Uveitis indication; updated dosing and quantity limits; updated HCPCS coding
07.31.2019	Updated criteria that trial of preferred biologics only applies to non-preferred biologics
06.07.2019	Updates to TB skin test requirements for apremalist; updates to initial authorization clinical criteria
11.02.2018	Addition of Hyrimoz (adalimumab-adaz)
09.07.2018	Addition of new medication
08.16.2017	New Policy