Ustekinumab IV (Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Wezlana, Yesintek)

Policy Number: MC/PC 049
Effective Date: June 1, 2026

Instructions for Use

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Related Policies

- n/a

Coverage Rationale

This policy refers to the following ustekinumab products for intravenous infusion only:

- Stelara (ustekinumab) injection, for intravenous use
- Imuldosa (ustekinumab-srlf) injection, for intravenous use
- Otulfi (ustekinumab-aauz) injection, for intravenous use
- Pyzchiva (ustekinumab-ttwe) injection, for intravenous use
- Selarsdi (ustekinumab-aekn) injection, for intravenous use
- Steqeyma (ustekinumab-stba) injection, for intravenous use
- Wezlana (ustekinumab-auub) injection, for intravenous use
- Yesintek (ustekinumab-kfce) injection, for intravenous use

Crohn's Disease

For initial coverage of ustekinumab IV for Crohn's Disease, the following will be required:

- Diagnosis of moderately to severely active Crohn's disease **and**
- One of the following:
  - Frequent diarrhea and abdominal pain
  - At least 10% weight loss
  - Complications such as obstruction, fever, abdominal mass
  - Abnormal lab values (e.g., C-reactive protein [CRP])
  - CD Activity Index (CDAI) greater than 220 **and**
- Medication is to be administered as an intravenous induction dose **and**

- Medication induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:
    - 260 mg for patients weighing 55 kg or less
    - 390 mg for patients weighing more than 55 kg to 85 kg
    - 520 mg for patients weighing more than 85 kg **and**
- Prescribed by or in consultation with a gastroenterologist

Ulcerative Colitis:

For initial coverage of ustekinumab IV for Ulcerative Colitis, the following will be required:

- Diagnosis of moderately to severely active ulcerative colitis **and**
- One of the following:
    - Greater than 6 stools per day
    - Frequent blood in the stools
    - Frequent urgency
    - Presence of ulcers
    - Abnormal lab values (e.g., hemoglobin, erythrocyte sedimentation rate [ESR], CRP)
    - Dependent on, or refractory to, corticosteroids **and**
- Medication is to be administered as an intravenous induction dose **and**
- Medication induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for ulcerative colitis:
    - 260 mg for patients weighing 55 kg or less
    - 390 mg for patients weighing more than 55 kg to 85 kg
    - 520 mg for patients weighing more than 85 kg **and**
- Prescribed by or in consultation with a gastroenterologist

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
C9399	Unclassified drugs or biologicals used in the outpatient hospital setting
J3358	Ustekinumab for intravenous injection, 1 mg
J3590	Unclassified biologics
Q5098	Injection, ustekinumab-srlf (Imuldosa), biosimilar, 1 mg
Q5099	Injection, ustekinumab-stba (Steqeyma), biosimilar, 1 mg
Q5100	Injection, ustekinumab-kfce (Yesintek), biosimilar, 1 mg
Q5138	Injection, ustekinumab-auub (Wezlana), biosimilar, intravenous, 1 mg
Q9997	Injection, ustekinumab-ttwe (Pyzchiva), intravenous, 1 mg
Q9998	Injection, ustekinumab-aekn (Selarsdi), 1 mg
Q9999	Injection, ustekinumab-aauz (Otulfi), biosimilar, 1 mg

ICD-10 Code	Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complication
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction

ICD-10 Code	Description
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication

ICD-10 Code	Description
K51.419	Inflammatory polyps of colon with unspecified complications

Background

Ustekinumab is a human IgG1κ monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL-23 naturally occurring cytokines. IL-12 and IL-23 are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation.

Clinical Evidence

Crohn's Disease

The use of Stelara (ustekinumab) for the treatment of CD was evaluated in the UNITI-1, UNITI-2, and IM-UNITI studies (Feagan et al 2016). All were Phase 3, double-blind, placebo-controlled trials.

- UNITI-1 (n = 741) was an 8-week induction trial that compared single IV doses of ustekinumab 130 mg, weight-based ustekinumab (~6 mg/kg), and placebo in patients with nonresponse or intolerance to ≥ 1 TNF inhibitors. The primary endpoint was clinical response at week 6, which was defined as a decrease from baseline in the CDAI of ≥ 100 points or a CDAI score of < 150. A clinical response was achieved by 34.4%, 33.7%, and 21.5% of patients in the ustekinumab 130 mg, weight-based ustekinumab, and placebo groups, respectively (p = 0.002 for 130 mg dose vs placebo; p = 0.003 for weight-based dose vs placebo). Benefits were also demonstrated on all major secondary endpoints, which included clinical response at week 8, clinical remission (CDAI < 150) at week 8, and CDAI decrease of ≥ 70 points at weeks 3 and 6.
- UNITI-2 (n = 628) had a similar design to UNITI-1 but was conducted in patients with treatment failure or intolerance to immunosuppressants or glucocorticoids (with no requirement for prior TNF inhibitor use). In this trial, a clinical response was achieved by 51.7%, 55.5%, and 28.7% of patients in the ustekinumab 130 mg, weight-based ustekinumab, and placebo groups, respectively (p < 0.001 for both doses vs placebo). Benefits were also demonstrated on all major secondary endpoints.
- IM-UNITI was a 44-week maintenance trial that enrolled patients completing UNITI-1 and UNITI-2. Of 1281 enrolled patients, there were 397 randomized patients (primary population); these were patients who had had a clinical response to ustekinumab induction therapy and were subsequently randomized to ustekinumab 90 mg SC every 8 or 12 weeks or placebo. The primary endpoint, clinical remission at week 44, was achieved by 53.1%, 48.8%, and 35.9% of patients in the ustekinumab every 8 week, ustekinumab every 12 week, and placebo groups, respectively (p = 0.005 for every 8 week regimen vs placebo; p = 0.04 for every 12 week regimen vs placebo). Numerical and/or statistically significant differences for ustekinumab vs placebo were observed on key secondary endpoints including clinical response, maintenance of remission, and glucocorticoid-free remission. Patients receiving SC ustekinumab maintained clinical remission through 5 years with no new safety signals observed (Sandborn et al 2022).

Ulcerative Colitis

The efficacy of Stelara (ustekinumab) as induction and maintenance therapy in 961 patients with moderate to severe UC was evaluated in a study (Sands et al 2019). The study involved 8-week induction and 44-week maintenance phases. Patients were randomly assigned to receive an IV induction dose of either ustekinumab 130 mg (n = 320), a weight-range-based ustekinumab dose that approximated 6 mg/kg (n = 322), or placebo (n = 319). Patients with an induction response were then randomly assigned to ustekinumab 90 mg SC every 12 weeks (n = 172), every 8 weeks (n = 176), or placebo (n = 175) for maintenance. Results revealed a significantly higher clinical remission at week 8 with ustekinumab 130 mg (15.6%) or 6 mg/kg (15.5%) as compared to placebo (5.3%; p < 0.001 for both comparisons). At the end of maintenance, the percentage of patients who had clinical remission was also significantly increased in both ustekinumab groups (38.4% for every 12 weeks vs 43.8% for every 8 weeks vs 24% for placebo; p = 0.002 and p < 0.001, respectively).

- A 3-year long-term extension of the UNIFI study reported on the safety and efficacy of Stelara (ustekinumab) 90 mg given SC every 12 (n = 141) or 8 weeks (n = 143) (Abreu et al 2022). Dosage adjustments were allowed for patients receiving every 12 week dosing in the study from week 56 onward, and during the study, 42.6% of patients went from every 12 week to every 8 week dosing. By week 52, patients with a history of biologic failure were found to experience lower rates of remission than biologic-naïve patients. Among those in remission at the long-term extension study baseline, 53.3% receiving every 12 week dosing and 53.8% receiving every 8 week dosing remained in symptomatic remission through week 152. At the long-term extension study baseline, 51.7% and 46% of patients in the every 12 week and every 8 week dosing groups were corticosteroid-free, respectively. By week 152, 51.2% and 55.2% of patients were corticosteroid-free in the every 12 week and every 8 week dosing groups, respectively. Approximately 80% of ustekinumab-treated patients continued treatment through 3 years, with no new safety signals reported.
- Four-year long-term results of this extension of the UNIFI study were published in 2024. By week 200, 55.2% of patients randomized to SC ustekinumab at maintenance baseline were in symptomatic remission. A greater proportion of biologic-naïve patients (67.2%) were in remission than those with a history of biologic failure prior to randomization (41.6%). Of those patients in remission at week 200, 96.4% were corticosteroid-free. Long-term efficacy of ustekinumab was confirmed through year 4, with no new safety signals reported (Afif et al 2024).

Clinical Guidelines

Crohn's Disease

- A 2025 American College of Gastroenterology (ACG) guideline on the management of CD in adults recommends controlled ileal release budesonide at a dose of 9 mg once daily for induction of symptomatic remission for patients with mild to moderate ileocecal CD (Lichtenstein et al 2025).
    - For mild to moderate disease and those at lower risk for progression, the guideline also recommends against the use of oral mesalamine to treat patients with active CD, since it has not consistently been shown effective for inducing remission and achieving mucosal healing when compared to placebo. Sulfasalazine should only be considered for patients with symptomatic mild colonic CD.
    - For patients with moderate to severe disease, ACG recommends oral corticosteroids for short-term induction of remission and against induction with azathioprine and mercaptopurine; however, azathioprine and mercaptopurine are suggested as an option for maintenance of remission following induction with corticosteroids. Methotrexate is also suggested for maintenance of remission following induction with corticosteroids. The TNF inhibitors adalimumab, certolizumab, and infliximab are recommended for induction and maintenance of remission. Due to the potential for immunogenicity and loss of response to TNF therapy, combination with immunotherapy may be considered. The combination of infliximab with an immunomodulator (thiopurine) is more effective than monotherapy with individual agents in patients with moderate to severe CD and who are naïve to both agents. Subcutaneous infliximab is an option for maintenance of remission following IV infliximab induction. Vedolizumab can be used for induction and maintenance of remission in patients with moderate to severe CD, and SC vedolizumab may be considered as a maintenance option in patients who respond to 2 doses of IV vedolizumab induction. Ustekinumab and risankizumab are also recommended as options for induction and maintenance of remission, with risankizumab being preferred over ustekinumab in patients with prior TNF inhibitor therapy. Other recommended options for induction and maintenance of remission include mirikizumab and SC guselkumab (with option to use IV for induction). Upadacitinib is recommended for induction and maintenance of remission in patients who were exposed to prior TNF therapy.
    - In patients with fistulizing CD, infliximab is recommended for induction of remission. Other options that are suggested include adalimumab, vedolizumab, ustekinumab, and upadacitinib.
    - The guideline acknowledges the effectiveness of biosimilars of infliximab, adalimumab, and ustekinumab for the management of moderate to severe CD, as well as the safety and efficacy of transitioning to a biosimilar infliximab or adalimumab in patients with stable disease.

- A 2025 AGA living guideline on the pharmacologic management of moderate to severe CD suggests upfront use of advanced therapies, rather than step-up therapy after corticosteroids and/or immunomodulator monotherapy in adult outpatients with moderate to severely active CD (Scott et al 2025). This AGA guideline is not intended for the management of postoperative, perianal, or internally penetrating or structuring CD.
    - The use of infliximab, adalimumab, ustekinumab, risankizumab, mirikizumab, guselkumab, or upadacitinib is recommended over no treatment. The use of certolizumab pegol or vedolizumab is suggested over no treatment. In terms of their efficacy in therapy selection, the biosimilars of infliximab, adalimumab, and ustekinumab can be considered equivalent to their originator drug.
    - In adult outpatients who are naïve to advanced therapies, the AGA suggests using higher-efficacy medications (infliximab, adalimumab, vedolizumab, ustekinumab, risankizumab, mirikizumab, guselkumab) rather than lower-efficacy medications (certolizumab pegol, upadacitinib).
    - In patients who have been previously exposed to ≥ 1 advanced therapies, particularly TNF antagonists, the use of a higher efficacy medication (adalimumab, risankizumab, guselkumab, upadacitinib) or an intermediate efficacy medication (ustekinumab, mirikizumab) rather than a lower efficacy medication (vedolizumab, certolizumab pegol) is suggested by the AGA.
    - The AGA suggests against using thiopurine monotherapy over no treatment for inducing remission in adult outpatients with moderate to severely active CD. In patients who have achieved remission, thiopurine monotherapy is suggested over no treatment to maintain remission.
    - In patients naïve to thiopurines and starting infliximab, the use of infliximab in combination with thiopurines rather than infliximab monotherapy is suggested. The AGA makes no recommendation on the use of adalimumab in combination with thiopurines or methotrexate over adalimumab monotherapy. The AGA also makes no recommendation, in favor of or against, on the use of non-TNF-targeting biologics (vedolizumab, ustekinumab, risankizumab, mirikizumab, guselkumab) in combination with thiopurines or methotrexate or corresponding biologic monotherapy.

- The 2024 ECCO guideline on medical treatment in CD recommends the use of infliximab, adalimumab, ustekinumab, risankizumab, vedolizumab, and upadacitinib to induce remission and maintenance of remission in patients with moderate-to-severe CD (Gordon et al 2024). Other immunomodulator-related recommendations within the guideline include:
    - Recommending combination therapy with infliximab and thiopurines when starting infliximab as induction therapy in patients with moderate-to-severe CD and recommending combination therapy for a minimum of 6 to 12 months.
    - Suggesting against the combination of adalimumab and thiopurines over adalimumab alone to achieve clinical remission and response.
    - Suggesting certolizumab can be used as induction therapy and maintenance therapy in moderate-to-severe CD.
    - Suggesting adalimumab or ustekinumab are equally effective as induction and maintenance therapy in biologic-naïve patients with moderate-to-severe CD.

Ulcerative Colitis

- A 2025 guideline from the American College of Gastroenterology (ACG) recommends 5-ASA therapy for induction of remission in mildly active UC, and budesonide, systemic corticosteroids, S1P receptor modulators (ozanimod and etrasimod), ustekinumab, IL-23p19 inhibitors (guselkumab, mirikizumab, and risankizumab), TNF inhibitors (infliximab in combination with a thiopurine, adalimumab, and golimumab), vedolizumab, and JAK inhibitors (tofacitinib and upadacitinib) for induction of remission in moderately to severely active disease. For maintenance of remission in patients with previously mildly active disease, 5-ASA therapy is recommended. In patients with previously moderately to severely active disease, continuation of TNF inhibitor, S1P receptor modulator, ustekinumab, guselkumab, mirikizumab, risankizumab, infliximab (in combination with a thiopurine), vedolizumab, or JAK inhibitor therapy is recommended after induction of remission with these agents.

Thiopurines may be used after corticosteroid induction in patients with moderate to severe UC (Rubin et al 2025).

- For adult outpatients with moderate to severe UC, an American Gastroenterological Association (AGA) living guideline was last updated in 2024, and recommends using infliximab, golimumab, vedolizumab, tofacitinib, upadacitinib, ustekinumab, ozanimod, etrasimod, risankizumab, and guselkumab over no treatment and suggests use of adalimumab, filgotinib (not approved in the U.S.) or mirikizumab over no treatment (Singh et al 2024). Biosimilars of infliximab, adalimumab, and ustekinumab are considered equivalent to the reference drug. Subcutaneous formulations of infliximab and vedolizumab have comparable efficacy to the intravenous maintenance doses. In patients with severe disease, extended induction regimens up to 16 weeks or dose escalation may be beneficial for certain agents. In patients with moderate to severe UC naïve to advanced therapies, the AGA suggests using a higher efficacy medication (infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, guselkumab) or an intermediate efficacy medication (golimumab, ustekinumab, tofacitinib, filgotinib, mirikizumab), instead of a lower efficacy medication (adalimumab). JAK inhibitors may be associated with higher risk of major adverse cardiovascular events and cancer than TNF antagonists in older adults with cardiovascular risk factors. JAK inhibitors are recommended in those with failure or intolerance to TNF antagonists. Vedolizumab and anti-IL therapies may be associated with a lower infection risk than TNF antagonists and may be preferred in those at risk of immunosuppression-related infections or malignancies. JAK inhibitors and S1P receptor modulators should be avoided in women of childrearing age contemplating pregnancy.

- The European Crohn's and Colitis Organisation (ECCO) recommends thiopurines for maintenance of remission in patients with steroid-dependent UC who are intolerant of 5-ASA. Remission can be induced with TNF inhibitors, vedolizumab, tofacitinib, or ustekinumab in patients with moderate to severe disease that has not responded to conventional therapy. Remission can be maintained with the same biologic agent that was used for induction therapy (Raine et al 2022).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Imuldosa is a human interleukin-12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

Otulfi is a human interleukin-12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

Pyzchiva is a human interleukin-12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

Selarsdi is a human interleukin-12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy.
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients (6 years or older) with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

Steqeyma is a human interleukin-12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

Wezlana is a human interleukin -12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

Yesintek is a human interleukin-12 and -23 antagonist indicated for the treatment of:
Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA)

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19. Steqeyma. Package insert. Celltrion USA; December 2025.
20. Wezlana. Package insert. Amgen; October 2025.
21. Yesintek. Package insert. Biocon Biologics; January 2026.

Policy History/Revision Information

Date	Summary of Changes
12/13/2023	Approved by OptumRx P&T Committee
10/16/2024	Annual Review. All sections updated to reflect IV formulation only. Updated references.
07/16/2025	Annual review. Addition of biosimilar products, leading to change of name in policy. Updates to all sections.
09/17/2025	Addition of Steqeyma to policy. Update to coverage rationale section, HCPCS codes, US FDA and reference sections to include Steqeyma
05/14/2026	Addition of Imuldosa to policy. Update to coverage rationale section, HCPCS codes, US FDA and reference sections to include Imuldosa. Additional updates to background, clinical guidelines, and references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).