Effective Date: 2/19
Reviewed: 2/2019, 1/2020, 4/2020, 11/2020, 12/2020, 5/2021, 01/2022, 2/2022, 7/2022, 12/2022, 8/2023, 2/2024, 1/2025, 4/2025, 7/2025, 8/2026 Scope: Medicaid

Ustekinumab Biosimilar SC Products: Otulfi (ustekinumab-aauz), Selarsdi (ustekinumab-aekn), Steqeyma (ustekinumab-stba), Yesintek (ustekinumab-kfce)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderate to severe plaque psoriasis (PsO) in adults and pediatric patients 6 years of age or older
2. Active psoriatic arthritis (PsA) in adults and pediatric patients 6 years of age or older
3. Moderately to severely active Crohn's disease (CD) in adults and pediatric patients 2 years or older
4. Moderately to severely active ulcerative colitis (UC) in adults

Compendial uses:

1. Hidradenitis suppurativa in adults

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND
  Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Ustekinumab will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Tremfya (guselkumab), Icotyde (icotrokinra), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.); AND

- If the request is for Stelara SC, the member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab SC biosimilar at maximum tolerated doses.

Formulary ustekinumab biosimilar will pay within the quantity limit if there is at least one paid claim of at least a 30-day supply within the last 365 days for a biologic (e.g., Bimzelx, Cosentyx, Otezla, Rinvoq, Skyrizi, Taltz, Tremfya)

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 6 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:

1. Member is 6 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology; AND
3. Documentation has been submitted of one or more of the following:
    a. BSA affected is at least 10%; OR
    b. Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
    c. Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene); AND
4. Documentation has been submitted that the member meets any of the following criteria:
    a. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine or acitretin); OR
    b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
    c. Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND
5. If the member is 18 years of age or older, documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses; AND
6. Dosing falls within the FDA approved guidelines.

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for treatment of active psoriatic arthritis when all of the following criteria are met:

1. Member is 6 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Documentation has been submitted indicating one of the following criteria:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response, intolerance, or contraindication to methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.) despite adequate dosing; OR
        ii. Member has enthesitis or predominantly axial disease; OR
    b. Member has severe disease; AND
4. If the member is 18 years of age or older, documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses; AND

5. Dosing falls within the FDA approved guidelines.

C. Moderately to severely active Crohn's disease (CD)

Authorization of 6 months may be granted for treatment of moderately to severely active Crohn's disease when all of the following criteria are met:

1. Member is 2 years of age or older; AND
2. Member has documented moderate to severe active disease; AND
3. Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
4. If the member is 6 years of age or older, documentation has been submitted that member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses

D. Moderately to severely active ulcerative colitis (UC)

Authorization of 6 months may be granted for treatment of moderately to severely active UC when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Member has documented moderate to severe UC; AND
3. Prescribed by, or in consultation with, a specialist in gastroenterology; AND
4. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses.

E. Hidradenitis suppurativa

Authorization of 6 months may be granted for treatment of hidradenitis suppurativa when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Documentation has been submitted that the member meets all of the following criteria:
   a. Member has had an inadequate response, intolerance, or contraindication to oral antibiotics for at least 90 days; AND
   b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

IV. CONTINUATION OF THERAPY

Formulary ustekinumab biosimilar will continue to pay within the quantity limit after the initial approval if there is at least one paid claim of at least a 30-day supply within the last 365 days for formulary ustekinumab; OR

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 6 months may be granted for all members 6 years of age and older (including new members) with documentation who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease

activity (e.g., reduction in BSA from baseline) or improvement in signs and symptoms of the condition (e.g., itching, redness, flaking, scaling, burning, cracking, pain).

B. Active psoriatic arthritis (PsA)

Authorization of 6 months may be granted for all members 6 years of age or older (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Moderately to severely active Crohn's disease (CD)

Authorization of 6 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition baseline (e.g., abdominal pain or tenderness, diarrhea, body weight, abdominal mass, hematocrit, endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score).

D. Moderately to severely active ulcerative colitis

Authorization of 6 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition baseline (e.g., stool frequency, rectal bleeding, urgency of defecation, C-reactive protein (CRP), fecal calprotectin (FC), endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score).

E. Hidradenitis suppurativa

Authorization of 6 months may be granted for all members (including new members) with documentation who are using the requested medication for moderate to severe hidradenitis

suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

V. OTHER

Induction:

Ustekinumab for intravenous administration is FDA-approved for the treatment of Crohn's disease and ulcerative colitis and will only be authorized for these conditions as a single dose within the FDA guidelines.

- ≤ 55 kg: 260 mg
- > 55 kg to 85 kg: 390 mg
- > 85 kg: 520 mg

Maintenance:

The recommended subcutaneous maintenance dosage for Crohn's disease and ulcerative colitis is 90 mg administered 8 weeks after the initial intravenous dose.

Note: If requesting IV dose, this must be indicated on the request with the following information:

A. Where drug will be obtained - through pharmacy benefit (filled at specialty pharmacy) or through medical benefit ('buy and bill')

B. Servicing provider name and NPI for ustekinumab administration if requesting through medical benefit

VI. QUANTITY LIMIT

Ustekinumab 45mg or 90mg dose – 1 injection per 6 weeks, post-limit for loading dose of 2 injections per 35 days

VII. DOSING

Indication	**Dose (subcutaneous)**
Adult patients with plaque psoriasis	Weight ≤100 kg: Initial: 45 mg; Week 4: 45 mg; then 45 mg every 12 weeks thereafter. Weight >100 kg: Initial: 90 mg; Week 4: 90 mg; then 90 mg every 12 weeks thereafter.
Pediatric patients (≥6 years) with plaque psoriasis	Weight <60 kg: Initial: 0.75 mg/kg; Week 4: 0.75 mg/kg; then every 12 weeks thereafter. Weight 60 kg to 100 kg: Initial: 45 mg; Week 4: 45 mg; then every 12 weeks thereafter. Weight >100 kg: Initial: 90 mg; Week 4: 90 mg; then every 12 weeks thereafter.
Adult patients with psoriatic arthritis (PsA)	Initial: 45 mg: Week 4: 45 mg; then 45 mg every 12 weeks thereafter. *Patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg*: Initial: 90 mg; Week 4: 90 mg; then 90 mg every 12 weeks thereafter.
Pediatric patients (≥6 years) with psoriatic arthritis (PsA)	Weight <60 kg: Initial: 0.75 mg/kg; Week 4: 0.75 mg/kg; then every 12 weeks thereafter. Weight ≥60 kg: Initial: 45 mg; Week 4: 45 mg; then every 12 weeks thereafter. *Weight >100 kg with co-existent moderate-to-severe plaque psoriasis:* Initial: 90 mg; Week 4: 90 mg; then every 12 weeks thereafter.
Adult patients with Crohn's disease (CD)	Following a single weight-based intravenous induction dose: Week 8: 90 mg Every 8 weeks thereafter: 90 mg
Pediatric patients (2 years and older) with Crohn's disease (CD)	Following a single weight-based intravenous induction dose: Weight 10 kg to 35 kg: Week 8: 2.5 mg/kg; every 8 weeks thereafter: 2.5 mg/kg. Weight >35 kg: Week 8: 90 mg; every 8 weeks thereafter: 90 mg.
Adult patients with ulcerative colitis (UC)	Following a single weight-based intravenous induction dose: Week 8: 90 mg Every 8 weeks thereafter: 90 mg

VIII. REFERENCES

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