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Policy Number: 029.005

Title: Coverage Determination Policy for Stelara (Ustekinumab)

Regions:	☒ **Texas**	☐ **Florida**	☐ **Indiana**	☐ **New Jersey**	☒ **New Mexico**

Impacted Areas:

☒ Network Management/Provider Services	☒ Utilization Management
☐ Member services	☐ Case management
☐ Quality Management	☐ Disease management
☐ Credentialing	☒ Claims
☐ IT	☐ Human resources
☐ Administration	☐ Finance
☐ Compliance/delegation	☒ Pharmacy
	☐ ALL

Available LCD/NCD/LCA: None

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Coverage Policy Number: 029.005

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage Determination:

Initial/New Requests

Precaution: It is recommended to evaluate patients for TB (tuberculin skin test) prior to therapy. Treatment of latent infection should be started prior to Stelara therapy

The following criteria are applicable to ALL indications in addition to indication specific criteria below:

All requests for subcutaneous ustekinumab must include documented medical justification as to why the patient is unable to self-administer subcutaneous doses. Requests for subcutaneous ustekinumab should generally be covered under the member's pharmacy benefit

- Medicare rules expect that if a patient is *clinically able* to self-administer a drug and there is no clear medical justification to do otherwise. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf
- The following factors are considered unrelated to medical decision making:
  - Patient convenience
  - Patient co-pays and financial liability

Crohn's disease (Moderate to Severe) when **ALL** of the following criteria are met:

A. Diagnosis of moderately to severely active Crohn's disease

B. Patient meets **ONE** of the following:

I. Patient has a history of failure to at least one of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced

a. Immunosuppressants (6-mercaptopurine, azathioprine, methotrexate)

b. Corticosteroids (Prednisone, methylprednisolone, budesonide)

II. Patient has been previously treated with a biologic DMARD FDA-approved for the treatment of Crohn's disease (see Biologic/DMARDs chart on page 11)

C. Dosing is in accordance with FDA approved labeled dosing for Crohn's disease

D. Stelara is to be administered as a single intravenous induction dose

E. Patient is NOT receiving Stelara® in combination with ANY of the following:

I. Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

II. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

Plaque psoriasis (Moderate to Severe) when **ALL** of the following criteria are met:

A. Diagnosis of moderate to severe plaque psoriasis

B. **ONE** of the following:

I. Patient meets **ALL** of the following criteria below:

a. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

b. History of failure to **ONE** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced:

i. Corticosteroids (e.g., betamethasone, clobetasol, desonide)

ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)

iii. Tazarotene

iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

v. Anthralin

vi. Coal tar

c. History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced

OR

II. Patient has been previously treated with a biologic or targeted synthetic DMARD* FDA-approved for the treatment of plaque psoriasis (see Biologic/DMARDs chart on page 11)

OR

III. Patient is currently on Stelara

C. Dosing is in accordance with FDA approved labeled dosing for plaque psoriasis

D. Prescriber attestation that patient or caregiver are not able to be trained or are physically unable to administer Steleara FDA labeled for self administration

E. Patient is NOT receiving Stelara® in combination with ANY of the following:

I. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

II. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

III. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Psoriatic arthritis, Active, alone or in combination with methotrexate when **ALL** of the following criteria are met:

A. Diagnosis of active psoriatic arthritis

B. Patient meets **ONE** of the following:

I. History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced

II. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis [e.g., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Otezla (apremilast)] See Biologic/DMARDs chart on page 11.

III. Patient is currently on Stelara

C. Dosing is in accordance with FDA approved labeled dosing for plaque psoriasis

D. Prescriber attestation that patient or caregiver are not able to be trained or are physically unable to administer Steleara FDA labeled for self administration

E. Patient is NOT receiving Stelara in combination with ANY of the following:

I. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

II. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

III. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Ulcerative colitis (Moderate to Severe), Active when **ALL** of the following criteria are met:

A. Diagnosis of moderately to severely active ulcerative colitis

B. Patient meets **ONE** of the following:

I. Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

II. Patient has been previously treated with a biologic DMARD FDA-approved for the treatment of Ulcerative colitis [e.g., Humira (adalimumab), Simponi (golimumab), Xeljanz (tofacitinib)]. See Biologic/DMARDs chart on page 11, (document drug, date, and duration of trial)

C. Stelara is to be administered as a single intravenous induction dose

D. Induction dosing is in accordance with FDA approved labeled dosing for ulcerative colitis.

E. Patient is NOT receiving Stelara® in combination with ANY of the following:

I. Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

II. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib) , Olumiant (baricitinib)]

Note: Stelara (ustekinumab) is unproven and not medically necessary for the treatment of Ankylosing spondylitis and Multiple sclerosis

Renewal/Continuation of Therapy Requests

Renewal requests for continued use of Stelara (ustekinumab) for all indications will be approved when **ALL** of the following are met:

A. Prescriber attestation that the patient or caregiver are not able to be trained or are physically unable to administer subcutaneous Stelara

B. The patient has documented significant improvement with prior courses of treatment

C. Dosing is in accordance with FDA approved labeled dosing per indication

D. The patient still meets indication specific criteria above with the exception of diagnosis of moderate-to-severe/active disease

FDA Approved Dose and Indications

Indication	Dosing
Crohn's disease (Moderate to Severe)	• **Note: Authorization will be approved for one IV induction dose. *Requests for subsequent subcutaneous ustekinumab should generally be directed to the member's pharmacy benefit.*** • **(55 kg or less)** Induction, 260 mg IV as a single dose; maintenance, followed 8 weeks later with 90 mg subQ every 8 weeks • **(Greater than 55 kg to 85 kg)** Induction, 390 mg IV as a single dose; maintenance, followed 8 weeks later with 90 mg subQ every 8 weeks • **(Greater than 85 kg)** Induction, 520 mg IV as a single dose; maintenance, followed 8 weeks later with 90 mg subQ ever 8 weeks • **Off-label dosage:** Low-dose induction: 130 mg IV as a single dose; if a response at week 8, proceed with maintenance, 90 mg subQ every 8 weeks
Plaque psoriasis (Moderate to Severe)	• **(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
Psoriatic arthritis, Active, alone or in combination with methotrexate	• 45 mg subQ initially and 4 weeks later, followed by 45 mg subQ every 12 weeks • Coexistent moderate to severe plaque psoriasis and weight greater than 100 kg, 90 mg subQ initially and 4 weeks later, followed by 90 mg subQ every 12 weeks
Ulcerative colitis (Moderate to Severe), Active	• **Note: Authorization will be approved for one IV induction dose. *Requests for subsequent subcutaneous ustekinumab should generally be directed to the member's pharmacy benefit.*** • **(55 kg or less)** Induction, 260 mg IV as a single dose; maintenance, 90 mg subQ every 8 weeks beginning 8 weeks after induction dose • **(Greater than 55 kg to 85 kg)** Induction, 390 mg IV as a single dose; maintenance, 90 mg subQ every 8 weeks beginning 8 weeks after induction dose • **(Greater than 85 kg)** Induction, 520 mg IV as a single dose; maintenance, 90 mg subQ every 8 weeks beginning 8 weeks after induction dose

General Background

Stelara (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 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. In in vitro models, ustekinumab was shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades by disrupting the interaction of these cytokines with a shared cell-surface receptor chain, IL-12 β1. Stelara is produced in a well characterized recombinant cell line and is purified using standard bio-processing technology. The manufacturing process contains steps for the clearance of viruses.

Ustekinumab is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy and for the treatment of adult patients with active psoriatic arthritis, either alone or with methotrexate.

Ustekinumab is also indicated for moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis in adult patients.

Ustekinumab is available as Stelara in 45 mg/0.5 mL and 90 mg/1 mL prefilled syringes or single-use vials and 130 mg/26 mL (5 mg/mL) intravenous solution in a single-dose vial.

Medicare does not have a National Coverage Determination (NCD) for Stelara® (ustekinumab). Local Coverage Determinations (LCDs) do not exist at this time. Medicare covers outpatient (Part B) drugs that are furnished “incident to” a physician’s service if the drugs are not usually self-administered by the patients who take them. Medicare requires not only that the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

Biologics/Targeted Synthetic DMARDs*	
Crohn's Disease	• Adalimumab (Humira) • Certolizumab (Cimzia) • Infliximab (Remicade) • Natalizumab (Tysabri) • Vedolizumab (Entyvio)
Plaque Psoriasis	• Adalimumab (Humira) • Certolizumab (Cimzia) • Etanercept (Enbrel) • Guselkumab (Tremfya) • Infliximab (Remicade) • Rizankizumab- rzaa (Skyrizi) • Ixekizumab (Taltz) • Secukinumab (Cosentyx) • Apremilast (Otezla) • Brodalumab (Siliq)
Psoriatic Arthritis	• Adalimumab (Humira) • Certolizumab (Cimzia) • Apremilast (Otezla) • Etanercept (Enbrel) • Golimumab (Simponi) • Abatacept (Orencia) • Ixekizumab (Taltz) • Secukinumab (Cosentyx) • Infliximab (Remicade) • Rizankizumab- rzaa (Skyrizi) • Guselkumab (Tremfya) • Tofactinib (Xeljanz)
Ulcerative Colitis	• Adalimumab (Humira) • Golimumab (Simponi) • Infliximab (Remicade) • Vedolizumab (Entyvio) • Tofactinib (Xeljanz)

This list is not all-inclusive*

Clinical Evidence

Crohn's disease (Moderate to Severe), Failed or intolerant to a tumor necrosis factor antagonist

Low-dose ustekinumab (130 mg IV once) provided similar 6-week clinical response and remission rates as weight-based induction (6 mg/kg IV once, up to 520 mg), and both doses were significantly better than placebo (response, 34.4% and 33.7% vs 21.5%; remission, 16.3% and 18.5% vs 8.9%) in the 8-week, randomized UNITI-1 trial in adults with disease resistant or intolerant to prior tumor necrosis factor (TNF)-antagonist therapy (N=741). In the subgroup analysis of patients from UNITI-1 who achieved a response (n=174) and entered the larger 44-week IM-UNITI maintenance trial (N=397), clinical remission rates with ustekinumab every 8 or 12 weeks were not significantly different than with placebo (41.1% and 38.6% vs 26.2%) in the patients with disease resistant or intolerant to prior TNF-antagonists.

Ustekinumab induction (6 mg/kg IV once) significantly improved clinical response rate compared with placebo at week 6 (39.7% vs 23.5%) in the randomized CERTIFI trial (N=526). Among those who responded to induction (n=145) ustekinumab maintenance (90 mg subQ every 8 weeks) significantly improved the clinical response (69.4% vs 42.5%) and remission rates (41.7% vs 27.4%) compared with placebo at week 22.

Crohn's disease (Moderate to Severe), Failed or intolerant to immunomodulators or corticosteroids

Low-dose ustekinumab (130 mg IV once) provided similar 6-week clinical response and remission rates as weight-based induction (6 mg/kg IV once, up to 520 mg), and both doses were significantly better than placebo (response, 51.7% and 55.5% vs 28.7%; remission, 28.7% and 34.9% vs 17.7%) in the 8-week, randomized UNITI-2 trial in adults with disease resistant or intolerant to prior immunosuppressant or glucocorticoid therapy (N=648). In the subgroup analysis of patients from UNITI-2 who achieved a response (n=214) and entered the larger 44-week IM-UNITI maintenance trial (N=397), ustekinumab 90 mg subQ every 8 weeks significantly improved remission rate at week 44 compared with placebo (62.5% vs 44.3%) but every 12 week dosing did not (56.9% vs 44.3%).

Plaque psoriasis (Moderate to Severe)

Overall drug survival (probability of staying on a drug over time) for ustekinumab was 84% at 1 year and 61% at 5 years in an analysis of adalimumab, etanercept, and ustekinumab from the Continuous Assessment of Psoriasis Treatment Use Registry with Biologics (BioCAPTURE). The study evaluated 526 treatment episodes of plaque psoriasis over 1333 treatment years with 102 episodes for ustekinumab. When considering ustekinumab survival rates by reason for discontinuation, survival at 5 years was 79% based on ineffectiveness and 83% based on adverse events. Higher BMI was a significant predictor for overall discontinuation of ustekinumab (43% more likely, 95% CI 1% to 103%) and discontinuation due to ineffectiveness (98% more likely, 95% CI 22% to 221%). For the 3 drugs considered together, female sex (45% more likely) and higher body mass index (18% more likely) were significant predictors of treatment discontinuation. Among patients with weight greater than 100 kg who discontinued ustekinumab

due to ineffectiveness, 83% were receiving the labeled 90-mg dose. The mean cumulative dose was 632 mg (69 mg every 12 weeks with weight 100 kg or less and 97 mg every 12 weeks with weight greater than 100 kg) and dose increases above the labeled dose occurred in 27% of patients.

In two 12-week, randomized trials (N=766; N=1230) a significantly greater proportion of patients treated with ustekinumab 45 or 90 mg (regardless of weight) achieved a 75% reduction in Psoriasis Area and Severity Index score (PASI 75) compared with placebo in study 1 (66.4% (90 mg) and 67.1% (45 mg) vs 3.1% with placebo) and in study 2 (75.7% (90 mg) and 66.7% (45 mg) vs 3.7% with placebo). A Physician's Global Assessment (PGA) rating of cleared or minimal was also achieved by a significantly greater proportion of ustekinumab-treated patients in study 1 (61% (90 mg) and 59% (45 mg) vs 4% with placebo) and in study 2 (73.5% (90 mg) and 68% (45 mg) vs 4.9% with placebo. At week 76, PASI 50, PASI 75, and PASI 90 responses were generally maintained while on ustekinumab.

In an evaluation of response by body weight, a PASI 75 in the ustekinumab 90 mg and 45 mg groups compared with placebo was significantly achieved by 65% and 74% versus 4% (100 kg or less), and 68% and 54% versus 2% (greater than 100 kg) in study 1. In study 2, PASI 75 occurred in 78% and 73% versus 4% (100 kg or less), and 71% and 49% versus 3% (greater than 100 kg). A PGA rating of cleared or minimal was also achieved by a significantly greater proportion of ustekinumab-treated patients in study 1 by 63% and 64% versus 4% (100 kg or less) and 58% and 49% versus 3% (greater than 100 kg). In study 2, PGA rating occurred in 75% and 74% versus 5% (100 kg or less), and 69% and 51% versus 3% (greater than 100 kg).

Psoriatic arthritis, Active, alone or in combination with methotrexate
Ustekinumab produced a greater proportion of American College of Rheumatology 20% improvement criteria (ACR20) responses in adults with active psoriatic arthritis despite NSAID or disease modifying antirheumatic therapy in 2 randomized studies (PSUMMIT 1 and PSUMMIT 2) , and which was maintained through week 100 in PSUMMIT 1.

Psoriatic arthritis, Active
Ustekinumab is recommended after failure of csDMARD of choice, Methotrexate, while TNFi is preferred as first line biologic. Oral small molecules, such as Methotrexate, are recommended to be started over IL-17i or IL-12/23i biologics in treatment naïve patients.

Ulcerative colitis (Moderate to Severe), Active
Ustekinumab was associated with significantly higher rates of clinical remission (total Mayo score of 2 or less with no subscore greater than 1) compared with placebo 8 weeks after an induction dose of approximately 6 mg/kg IV (15.5% vs 2.3%) and after 44 weeks of every-8-week subQ maintenance therapy (43.8% vs 24%) in a randomized study of adults with moderate to severe ulcerative colitis. After 44 weeks of maintenance therapy, ustekinumab was also associated with significantly higher rates of endoscopic improvement (51.1% vs 28.6%) and corticosteroid-free remission (42% vs 23.4%). During the 8-week induction phase, patients (N=961) were randomized to a single ustekinumab dose of either 130 mg or approximately 6 mg/kg IV or placebo. Those with a clinical response within 16 weeks of the induction dose entered into a 44-week maintenance phase (n=523) in which patients were randomized to ustekinumab 90 mg subQ

every 8 weeks or every 12 weeks or placebo. Also included in the maintenance phase were 260 nonrandomized patients who included those who had a delayed response to induction and were treated with ustekinumab during the maintenance phase, and those who had a response to placebo during induction and were given placebo subQ during the maintenance phase. About 45% were naïve to biologic treatment, all patients were required to have had an inadequate response to or unacceptable side effects from TNF antagonists, vedolizumab, or conventional therapy. Patients were allowed to continue stable doses of aminosalicylates and immunomodulators; corticosteroids were allowed during induction, but tapered during the maintenance phase. Cancer was reported in 0.8% patients treated with ustekinumab (prostate, colon, rectal, and non-melanoma skin cancer) and 0.3% of patients given placebo (testicular). Potential opportunistic infections were reported in 4 ustekinumab-treated patients (CMV colitis, legionella pneumonia, ophthalmic and oral herpes simplex).

HCPCS Code

HCPCS Code	Description	Dosage Form & Route of Administration	
J3357	Stelara (Ustekinumab)	Subcutaneous injection	45 mg/0.5 mL or 90 mg/1 mL single dose prefilled syringe 45 mg/0.5 mL single dose vial
J3358		Intravenous infusion	130 mg/26 mL solution in single dose vial

Acronyms

IL = Interleukin

NCD = National Coverage Determination

LCD = Local Coverage Determinations

TNF = Tumor Necrosis Factor

TB = Tuberculosis

DMARD = Disease Modifying Anti-rheumatic Drug

PASI 75 = Psoriasis Area and Severity Index score

SUBQ = Subcutaneous

NSAID = Non-Steroidal Anti-Inflammatory Drug

PGA = Physician's Global Assessment

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