Restricted Product(s):

- *ustekinumab (Stelara®) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- *Ustekinumab intravenous infusion and subcutaneous injection for administration by a healthcare professional
- ustekinumab-srlf (Imuldosa™) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- ustekinumab-aauz (Otulfi™) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- ustekinumab-ttwe (Pyzchiva®) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- *ustekinumab-aekn (Selarsdi™) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- ustekinumab-hmny (Starjemza™) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- *ustekinumab-stba (Steqeyma®) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- ustekinumab-auub (Wezlana™) intravenous infusion and subcutaneous injection for administration by a healthcare professional
- *ustekinumab-kfce (Yesintek™) intravenous infusion and subcutaneous injection for administration by a healthcare professional

***preferred agent**

FDA Approved Use:

- For the treatment of patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- For the treatment of patients 6 years of age and older with active psoriatic arthritis
- For the treatment of patients 2 years of age and older with moderately to severely active Crohn’s disease
- For the treatment of adults with moderately to severely active ulcerative colitis

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient has a diagnosis of moderate to severe **plaque psoriasis (PS)**; **AND**
    a. The patient is 6 years of age or older; **AND**
    b. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, phototherapy [e.g., PUVA, UVB], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **[medical record documentation required]**; **OR**

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c. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PS **[medical record documentation required]**; **OR**
d. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PS **[medical record documentation required]**; **OR**
e. The patient has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **[medical record documentation required]**; **OR**
f. The patient has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [e.g., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, rapidly progressive) **[medical record documentation required]**; **OR**
g. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of PS (excluding sample use) **[medical record documentation required]**; **AND**
    i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

2. The patient has a diagnosis of active **psoriatic arthritis (PsA)**; **AND**
    a. The patient is 6 years of age or older; **AND**
    b. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **[medical record documentation required]**; **OR**
    c. The patient has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **[medical record documentation required]**; **OR**
    d. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **[medical record documentation required]**; **OR**
    e. The patient has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [e.g., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, rapidly progressive) **[medical record documentation required]**; **OR**
    f. The patient has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **[medical record documentation required]**; **OR**
    g. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of PsA (excluding sample use) **[medical record documentation required]**; **AND**
        i. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **OR**

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3. The patient has a diagnosis of moderately to severely active **Crohn's disease (CD)**; **AND**
    a. The patient is 2 years of age or older and weighs at least 10 kg; **AND**
    b. ONE of the following:
        i. The patient has moderately to severely active disease, as evidenced by ONE of the following:
            1. The patient has BOTH of the following:
                a. Symptoms consistent with active CD (e.g., diarrhea, abdominal pain, significant weight loss, fatigue, fever, anemia, growth failure, vitamin or mineral deficiencies, intermittent nausea or vomiting, etc.) **[medical record documentation required]**; **AND**
                b. Evidence of active inflammation, confirmed by ONE of the following **[medical record documentation required]**:
                    i. Active inflammatory disease on cross-sectional imaging (MRE, CTE), intestinal ultrasound, or pelvic MRI for perianal disease (e.g., bowel wall thickening, ulceration, hyperenhancement, fistula, abscess); **OR**
                    ii. Biomarker evidence indicative of inflammation (e.g., elevated fecal calprotectin [FC], elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate [ESR], low serum albumin); **OR**
            2. Significant extent of disease or upper GI involvement identified on radiographic or endoscopic assessment (e.g., large or deep mucosal lesions, fistulas or perianal abscesses, intestinal strictures, extensive disease [ileal involvement >40 cm or pancolitis], prior bowel resection, etc.) **[medical record documentation required]**; **OR**
            3. Corticosteroid-dependence, or refractory to oral corticosteroids **[medical record documentation required]**; **OR**
        ii. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of CD (excluding sample use) **[medical record documentation required]**; **AND**
            1. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **AND**
    c. ONE of the following:
        i. If the request is for initiation of ustekinumab therapy, an initial intravenous infusion of an ustekinumab product will be administered; **OR**
        ii. If the request is for ustekinumab maintenance therapy, the patient has received an initial intravenous infusion of an ustekinumab product; **AND**
            1. For patients greater than 35 kg, the patient will be treated with the 90 mg injection; **OR**

4. The patient has a diagnosis of moderately to severely active **ulcerative colitis (UC)**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. ONE of the following:

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- i. The patient has moderately to severely active disease, as evidenced by ONE of the following:
  1. The patient has BOTH of the following:
     - a. Symptoms consistent with active UC (e.g., increased stool frequency, rectal bleeding, bowel urgency, nocturnal symptoms, abdominal pain and/or cramping, extraintestinal manifestations, significant weight loss, etc.) **[medical record documentation required]**; **AND**
     - b. Evidence of active inflammation or high-risk disease, confirmed by ONE of the following **[medical record documentation required]**:
       - i. Moderate to severe disease activity on a lower gastrointestinal endoscopy using a validated endoscopic assessment tool (e.g., Mayo Endoscopic Subscore [MES], Ulcerative Colitis Endoscopic Index of Severity [UCEIS] or equivalent); **OR**
       - ii. Evidence of active inflammatory disease on intestinal ultrasound (IUS), including findings consistent with active colitis (e.g., increased bowel wall thickness, hyperemia); **OR**
       - iii. Biomarker evidence indicative of inflammation (e.g., elevated fecal calprotectin [FC], elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate [ESR], low serum albumin); **OR**
       - iv. Presence of at least one poor prognostic factor (e.g., age younger than 40 years at diagnosis, extensive colitis, hospitalization for colitis); **OR**
  2. Corticosteroid-dependence, or refractory to oral corticosteroids **[medical record documentation required]**; **OR**
- ii. The patient is currently established on a biologic or systemic immunomodulator agent that is FDA approved for the treatment of UC (excluding sample use) **[medical record documentation required]**; **AND**
  1. The patient has had positive clinical benefit (e.g., improvement in signs and symptoms, reduction in disease severity, etc.) from use of the biologic or systemic immunomodulator agent **[medical record documentation required]**; **AND**

c. ONE of the following:
- i. If the request is for initiation of ustekinumab therapy, an initial intravenous infusion of an ustekinumab product will be administered; **OR**
- ii. If the request is for ustekinumab maintenance therapy, the patient has received an initial intravenous infusion of an ustekinumab product; **AND**
  1. The patient will be treated with the 90 mg injection; **AND**

5. If ustekinumab 90 mg is requested, ONE of the following:
   - a. The patient has a diagnosis of psoriasis; **AND**
     - i. The patient has tried and had an inadequate response to 45 mg for at least 3-months **[medical record documentation required]**; **OR**
     - ii. The patient weighs >100 kg **[medical record documentation required]**; **OR**
   - b. The patient has a dual diagnosis of psoriasis AND psoriatic arthritis; **AND**

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   i. The patient has tried and had an inadequate response to 45 mg for at least 3-months **[medical record documentation required]**; **OR**
   ii. The patient weighs >100 kg **[medical record documentation required]**; **OR**
  c. The patient has a diagnosis of Crohn's disease or ulcerative colitis; **AND**
6. If the request is for Imuldosa™ (ustekinumab-srlf), Otulfi™ (ustekinumab-aauz), Pyzchiva® (ustekinumab-ttwe), Starjemza™ (ustekinumab-hmny), Wezlana™ (ustekinumab-auub), or a non-preferred ustekinumab product, ONE of the following:
   a. The patient has tried and had an inadequate response to THREE of the following preferred ustekinumab products: Stelara® (ustekinumab), Ustekinumab, Selarsdi™ (ustekinumab-aekn), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce) **[medical record documentation required]**; **OR**
   b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to THREE the following preferred ustekinumab products that is NOT expected to occur with the requested agent: Stelara® (ustekinumab), Ustekinumab, Selarsdi™ (ustekinumab-aekn), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce) **[medical record documentation required]**; **AND**
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist for PS; rheumatologist for PsA; gastroenterologist for CD, UC) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
8. The patient will NOT be using the requested agent in combination with another biologic immunomodulator agent, Otezla® or Zeposia®; **AND**
9. The patient does NOT have any FDA labeled contraindications to ustekinumab (Stelara®, Ustekinumab), ustekinumab-srlf (Imuldosa™), ustekinumab-aauz (Otulfi™), ustekinumab-ttwe (Pyzchiva®), ustekinumab-aekn (Selarsdi™), ustekinumab-hmny (Starjemza™), ustekinumab-stba (Steqeyma®), ustekinumab-auub (Wezlana™), or ustekinumab-kfce (Yesintek™); **AND**
10. The patient has been tested for latent tuberculosis (TB) when required by the prescribing information for the requested agent AND if positive the patient has begun therapy for latent TB; **AND**
11. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
12. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval:

Crohn's disease and ulcerative colitis induction (IV): 60 days (one-time approval)
Crohn's disease and ulcerative colitis maintenance (SC): 365 days (1 year)
All other indications: 365 days (1 year)

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
ustekinumab (Stelara®) or Ustekinumab intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	J3357 (SC)	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight ≥ 60 kg: 45 mg Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		

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<table>
<tr><th colspan="5">FDA Label Reference</th></tr>
<tr><th>Medication</th><th>Indication</th><th>Dosing</th><th>HCPCS</th><th>Maximum Units*</th></tr>
<tr><td rowspan="2"></td><td>CD in patients ≥ 2 years old</td><td>IV: Induction therapy only; Single induction infusion
• weight 10 kg to 25 kg: 10 mg/kg
• weight > 25 kg to 55 kg: 260 mg
• weight > 55 kg to 85 kg: 390 mg
• weight > 85 kg: 520 mg

SC:
• weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter
• weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter</td><td rowspan="2">J3357 (SC)

J3358 (IV)</td><td rowspan="2">SC: 720

IV: 520</td></tr>
<tr><td>UC in patients ≥ 18 years old</td><td>IV: Induction therapy only; Single induction infusion
• weight ≤ 55 kg: 260 mg
• weight > 55 kg to 85 kg: 390 mg
• weight > 85 kg: 520 mg

SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter</td></tr>
<tr><td>ustekinumab-srlf (Imuldosa™)

intravenous (IV) infusion, subcutaneous (SC) injection</td><td>PS in patients ≥ 6 years old</td><td>Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks
• weight 60 kg to 100 kg: 45 mg
• weight > 100 kg: 90 mg

Adult SC: Administer at 0 and 4 weeks, then every 12 weeks
• weight ≤ 100 kg: 45 mg
• weight > 100 kg: 90 mg</td><td>Q5098</td><td>SC: 540</td></tr>
</table>

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≥ 60 kg: 45 mg Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: • weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter	Q5098	SC: 720 IV: 520
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg		

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
ustekinumab-aauz (Otulfi™) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	Q9999	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≥ 60 kg: 45 mg Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg	Q9999	SC: 720 IV: 520

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		SC: • weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
ustekinumab-ttwe (Pyzchiva®) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	Q9996 (SC)	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight ≥ 60 kg: 45 mg		

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: • weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter	Q9996 (SC) Q9997 (IV)	SC: 720 IV: 520
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
ustekinumab-aekn (Selarsdi™) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	Q9998	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight ≥ 60 kg: 45 mg Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg	Q9998	SC: 720 IV: 520

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		SC: • weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
ustekinumab-hmny (Starjemza™) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	C9399** J3490** J3590**	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight ≥ 60 kg: 45 mg		

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: • weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter	C9399** J3490** J3590**	SC: 720 IV: 520
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
ustekinumab-stba (Steqeyma®) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	Q5099	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≥ 60 kg: 45 mg Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC:	Q5099	SC: 720 IV: 520

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		• weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
ustekinumab-auub (Wezlana™) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	Q5137 (SC)	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight ≥ 60 kg: 45 mg		

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: • weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter	Q5137 (SC) Q5138 (IV)	SC: 720 IV: 520
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
ustekinumab-kfce (Yesintek™) intravenous (IV) infusion, subcutaneous (SC) injection	PS in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight 60 kg to 100 kg: 45 mg • weight > 100 kg: 90 mg Adult SC: Administer at 0 and 4 weeks, then every 12 weeks • weight ≤ 100 kg: 45 mg • weight > 100 kg: 90 mg	Q5100	SC: 540
	PsA in patients ≥ 6 years old	Pediatric SC: Administer at 0 and 4 weeks, then every 12 weeks • weight < 60 kg: 0.75 mg/kg • weight ≥ 60 kg: 45 mg Pediatric PS with PsA SC: weight >100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks Adult SC: 45 mg at 0 and 4 weeks, then every 12 weeks Adult PS with PsA SC: weight > 100 kg: 90 mg at 0 and 4 weeks, then every 12 weeks		
	CD in patients ≥ 2 years old	IV: Induction therapy only; Single induction infusion • weight 10 kg to 25 kg: 10 mg/kg • weight > 25 kg to 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg	Q5100	SC: 720 IV: 520

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
		SC: • weight 10 kg to 35 kg: 2.5 mg/kg 8 weeks after initial IV induction, then every 8 weeks thereafter • weight ≥ 35 kg: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		
	UC in patients ≥ 18 years old	IV: Induction therapy only; Single induction infusion • weight ≤ 55 kg: 260 mg • weight > 55 kg to 85 kg: 390 mg • weight > 85 kg: 520 mg SC: 90 mg 8 weeks after initial IV induction, then every 8 weeks thereafter		

***Maximum units allowed for duration of approval**
****Non-specific assigned HCPCS codes, must submit requested product NDC**

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

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***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    f. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
    g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol*. 2019;81(3):775-804.
2. Lichtenstein GR, Loftus EV Jr, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2025;120(6):1225-1264.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2025 Jun 3;120(6):1187-1224.
4. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025;169(7):1397-1448.
5. Singh S, Loftus EV, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024;167(7):1307-1343.

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Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

July 2026: Criteria change: For PS, PsA, CD, and UC: Added allowance for patients currently established on a biologic or systemic immunomodulator agent that is FDA approved for treatment of the requested indication for those who have had positive clinical benefit from use of the biologic or systemic immunomodulator agent. For PS: Adjusted phototherapy conventional agent option to include both PUVA and UVB as examples. For PsA and PS: Added additional examples defining long-term damage interfering with function associated with severe psoriatic arthritis. For CD: Removed required trial and failure of conventional therapy; Replaced allowance for severely active disease with required demonstration of moderately to severely active disease by documented presence of symptoms of active disease plus evidence of active inflammation OR significant extent of disease or upper GI involvement on radiographic or endoscopic assessment OR corticosteroid-dependence or refractory to oral corticosteroids; Changes made to align with updated clinical guidelines. For UC: Removed required trial and failure of conventional therapy; Replaced allowance for severely active disease with required demonstration of moderately to severely active disease by documented presence of symptoms of active disease plus evidence of active inflammation or high-risk disease (with associated confirmatory criteria) OR corticosteroid-dependence or refractory to oral corticosteroids; Changes made to align with updated clinical guidelines. Other minor formatting changes made throughout policy for clarity with no change to intent. **Policy notification given 5/1/2026 for effective date 7/1/2026**.
May 2026: Criteria change: Expanded Crohn's disease indication to patients 2 years and older. Adjusted criteria to include "for patients greater than 35 kg" for requirement that the patient will be treated with the 90 mg injection. Updated corresponding dosing information in dosing reference table with no change to maximum units.
November 2025: Criteria change: Updated Site of Care medical necessity criteria to add additional bypass for patients with a history of severe adverse events or conditions that cause an increased risk for severe adverse event to align with the Place of Service for Medical Infusions policy for clarity of intent.
August 2025: Criteria change: For CD: Updated policy to allow bypassing conventional agents for severely active Crohn's disease. Corrected preferred agent indicators in restricted products section to indicate current preferred products. Added new to market ustekinumab biosimilar Starjemza (ustekinumab-hmny) to policy for the same FDA approved indications as Stelara and with the same coverage criteria requirements. For Starjemza, added additional corresponding criteria as a non-preferred ustekinumab biosimilar product with requirement of trial and failure of three preferred agents [Stelara (ustekinumab), Ustekinumab (unbranded product), Selarsdi (ustekinumab-aekn), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)]. Added Starjemza to SOC criteria and added associated dosing, maximum units, and HCPCS codes C9399, J3490, J3590 to FDA label reference table.
July 2025: Coding change: For Imuldosa, added HCPCS code Q5098 to dosing reference table effective 7/1/2025; deleted C9399, J3490, and J3590 termed 6/30/2025. For Steqeyma, added HCPCS code Q5099 to dosing reference table effective 7/1/2025; deleted C9399, J3490, and J3590 termed 6/30/2025. For Yesintek, added HCPCS code Q5100 to dosing reference table effective 7/1/2025; deleted C9399, J3490, and J3590 termed 6/30/2025.

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July 2025: Criteria change: Added additional preferred ustekinumab products to the required trial and failure of three preferred agents [Ustekinumab (unbranded product), Selarsdi (ustekinumab-aekn), Steqeyma (ustekinumab-stba), and Yesintek (ustekinumab-kfce) added to existing preferred Stelara]; and adjusted non-preferred ustekinumab products to include Imuldosa (ustekinumab-srlf), Otulfi (ustekinumab-aauz), Pyzchiva (ustekinumab-ttwe), and Wezlana (ustekinumab-auub). Removed additional required trial and failure of two other preferred biologic agents.
May 2025: Criteria change: Added new to market unbranded Ustekinumab product to policy for the same FDA approved indications and HCPCS codes as Stelara, and with the same coverage criteria requirements. For unbranded Ustekinumab, added additional corresponding criteria as a non-preferred product with requirement of trial and failure of Stelara; and requirement of trial and failure of two of the following agents FDA approved for the requested indication: an adalimumab product, Cosentyx, Enbrel, Entyvio, Skyrizi, Tremfya, Otezla, Sotyktu, Rinvoq, Xeljanz/Xeljanz XR. Added new to market ustekinumab biosimilar Imuldosa (ustekinumab-srlf) to policy for the same FDA approved indications as Stelara, and with the same coverage criteria requirements. For Imuldosa, added additional corresponding criteria as a non-preferred ustekinumab biosimilar product with requirement of trial and failure of Stelara; and requirement of trial and failure of two of the following agents FDA approved for the requested indication: an adalimumab product, Cosentyx, Enbrel, Entyvio, Skyrizi, Tremfya, Otezla, Sotyktu, Rinvoq, Xeljanz/Xeljanz XR. Added unbranded Ustekinumab and Imuldosa to SOC criteria and added associated dosing, maximum units, and Imuldosa HCPCS codes C9399, J3490, J3590 to FDA label reference table.
March 2025v2: Criteria change: Added new to market ustekinumab biosimilar Otulfi (ustekinumab-aauz) to policy for the same FDA approved indications as Stelara and with the same coverage criteria requirements. For Otulfi, added additional corresponding criteria as a non-preferred ustekinumab biosimilar product with requirement of trial and failure of Stelara; and requirement of trial and failure of two of the following agents FDA approved for the requested indication: an adalimumab product, Cosentyx, Enbrel, Entyvio, Skyrizi, Tremfya, Otezla, Sotyktu, Rinvoq, Xeljanz/Xeljanz XR. Added Otulfi to SOC criteria and added associated dosing, maximum units, and HCPCS code Q9999 (effective 4/1/2025) to FDA label reference table.
March 2025: Criteria change: Added new to market ustekinumab biosimilar Selarsdi (ustekinumab-aekn) to policy for the same FDA approved indications as Stelara and with the same coverage criteria requirements. For Selarsdi, added additional corresponding criteria as a non-preferred ustekinumab biosimilar product with requirement of trial and failure of Stelara; and requirement of trial and failure of two of the following agents FDA approved for the requested indication: an adalimumab product, Cosentyx, Enbrel, Entyvio, Skyrizi, Tremfya, Otezla, Sotyktu, Rinvoq, Xeljanz/Xeljanz XR. Added Selarsdi to SOC criteria and added associated dosing, maximum units, and HCPCS code Q9998 to FDA label reference table.
February 2025v2: Criteria change: Added new to market ustekinumab biosimilar Pyzchiva (ustekinumab-ttwe) to policy for the same FDA approved indications as Stelara and with the same coverage criteria requirements. For Pyzchiva, added additional corresponding criteria as a non-preferred ustekinumab biosimilar product with requirement of trial and failure of Stelara; and requirement of trial and failure of two of the following agents FDA approved for the requested indication: an adalimumab product, Cosentyx, Enbrel, Entyvio, Skyrizi, Tremfya, Otezla, Sotyktu, Rinvoq, Xeljanz/Xeljanz XR. Added Pyzchiva to SOC criteria and added associated dosing, maximum units, and HCPCS codes Q9996 (SC) and Q9997 (IV) to FDA label reference table.

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February 2025: Criteria change: Added new to market ustekinumab biosimilars Steqeyma (ustekinumab-stba) and Yesintek (ustekinumab-kfce) to policy for the same FDA approved indications as Stelara and with the same coverage criteria requirements. For Steqeyma and Yesintek, added additional corresponding criteria as a non-preferred ustekinumab biosimilar product with requirement of trial and failure of Stelara; and requirement of trial and failure of two of the following agents FDA approved for the requested indication: an adalimumab product, Cosentyx, Enbrel, Entyvio, Skyrizi, Tremfya, Otezla, Sotyktu, Rinvoq, Xeljanz/Xeljanz XR. Added Steqeyma and Yesintek to SOC criteria and added associated dosing, maximum units, and HCPCS codes C9399, J3490, J3590 for each product to FDA label reference table.
January 2025: Criteria change: Added new to market ustekinumab biosimilar Wezlana (ustekinumab-auub) to policy for the same FDA approved indications as Stelara and with the same coverage criteria requirements. For Wezlana, added additional corresponding criteria as a non-preferred ustekinumab biosimilar product with requirement of trial and failure of Stelara; and requirement of trial and failure of two of the following agents FDA approved for the requested indication: an adalimumab product, Cosentyx, Enbrel, Entyvio, Skyrizi, Tremfya, Otezla, Sotyktu, Rinvoq, Xeljanz/Xeljanz XR. Added Wezlana to SOC criteria and added associated dosing, maximum units, and HCPCS codes Q5137 (SC) and Q5138 (IV) for Wezlana to FDA label reference table. Changed policy name to "Ustekinumab (Stelara®) and Ustekinumab Biosimilars" from "Ustekinumab (Stelara®)".
January 2024: Criteria update: Updated criteria related to specific dosing for Crohn's disease and ulcerative colitis indications to state "patient will be treated with the 90 mg injection" for clarity.
September 2023: Criteria change: For psoriatic arthritis: Removed hydroxychloroquine from list of conventional agents. For Crohn's disease: Removed aminosalicylates, mesalamine, and sulfasalazine from list of conventional agents. For ulcerative colitis: Updated policy to allow bypassing conventional agents for severely active ulcerative colitis; removed steroid suppositories from list of conventional agents. Separated out intolerance/hypersensitivity criteria from FDA labeled contraindication criteria for clarity. Added Zeposia as agent not to be used in combination with another biologic immunomodulator agent for clarity.
January 2023: Criteria change: Expanded psoriatic arthritis indication to patients 6 years and older, updated corresponding dosage in dosing reference table.
October 2021: Criteria change: Added Site of Care medical necessity criteria. **Policy notification given 8/2/2021 for effective date 10/1/2021**.
August 2021: Criteria change: Removed criteria points regarding medication history indicating use of another biologic immunomodulator agent FDA labeled for the treatment of the same condition. **Policy notification given 6/1/2021 for effective date 8/1/2021**.
June 2021: Criteria change: Medical record documentation required for all indications.
April 2021: Criteria change: Addition of criteria for history of use of another biologic immunomodulator agent (or Otezla) for the same indication; PS: BSA requirement changed to 10%, added option for concomitant severe PsA; PsA: added requirement for trial of one conventional agent, added option for severe active PsA or concomitant severe psoriasis; added requirements to be prescribed by or in consultation with a specialist, that patient has no FDA labeled contraindications, and for TB testing; added maximum units; medical policy formatting change. **Policy notification given 2/26/2021 for effective date 4/28/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.

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