CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Ustekinumab (Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana, Yesintek)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Stelara is a human interleukin-12 and interleukin-23 antagonist initially approved by the FDA in 2009. It is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. Pediatric patients 6 years and older are also approved to have Stelara for moderate to severe plaque psoriasis treatment. Multiple biosimilars have been approved for Stelara including Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana and Yesintek. They are indicated for the same indications as Stelara.

Ustekinumab (Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana, Yesintek) will be considered for coverage when the following criteria are met:

Crohn's Disease (CD)

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member has a diagnosis of moderately to severely active CD; AND
3. Medication must be prescribed by or in consultation with a gastroenterologist; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least **ONE** of the following conventional therapies. Note: trial is not required if member is switching from advanced therapy:
   a) Corticosteroid;
   b) 6-mercaptopurine, azathioprine or methotrexate; OR
5. Provider attests member has severe disease that requires immediate use of an advanced therapy (biologic, JAK inhibitor, etc.) agent such as penetrating or fistulizing disease, multiple resections, etc.; AND
6. If the request is for a non-preferred ustekinumab product, member has tried and failed three (3) preferred ustekinumab products (see appendix for preferred and non-preferred products); AND
7. Must have had a negative TB test within the last 12 months.
8. **Dosage allowed/Quantity limit:**
   a) Induction (medical benefit): a one-time IV infusion based on weight.

Weight (kilograms)	Recommended Dosage
55 kg or less	260 mg (2 vials)
Greater than 55 kg to 85 kg	390 mg (3 vials)
Greater than 85 kg	520 mg (4 vials)

   b) Maintenance (pharmacy or medical benefit): subcutaneous injection of 90 mg dose 8 weeks after induction and every 8 weeks thereafter.

Note to reviewer: A one-time induction dose is approved on the medical benefit. Maintenance therapy is approved on either pharmacy OR medical benefit. Please inactivate any duplicate prior authorization.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of CD (such as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member has tried and failed to respond to treatment with at least **ONE** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus);
   d) At least a 12-week trial of a systemic conventional DMARD (i.e., cyclosporine, methotrexate, acitretin); AND
5. If the request is for a non-preferred ustekinumab product, member has tried and failed three (3) preferred ustekinumab products (see appendix for preferred and non-preferred products); AND
6. Must have had a negative tuberculosis test within the last 12 months.
7. **Dosage allowed/Quantity limit:**
   a) Adults:
      i) 100 kg or less: 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter
      ii) More than 100 kg: 90 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter
   b) Pediatrics (6 to 17): subcutaneous dose by weight (see table below) at week 0, week 4, and every 12 weeks thereafter.

Weight Range (kilograms)	Dosage
Less than 60 kg	0.75 mg/kg
60 kg to 100 kg	45 mg
Greater than 100 kg	90 mg

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (such as documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:

1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Conventional DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional DMARD are **NOT** required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. If the request is for a non-preferred ustekinumab product, member has tried and failed three (3) preferred ustekinumab products (see appendix for preferred and non-preferred products); AND
6. Must have had a negative TB test within the last 12 months.
7. **Dosage allowed/Quantity limit:**
   a) Adults: 45 mg subcutaneously at 0 and 4 weeks, and then every 12 weeks thereafter. If member has co-existent moderate-to-severe PsO, use the dosing regimen for adult PsO.
   b) Pediatrics (6 to 17): subcutaneous dose by weight at week 0, week 4, and every 12 weeks thereafter.

Weight Range (kilograms)	Dosage
Less than 60 kg	0.75 mg/kg
60 kg or more	45 mg
Greater than 100 kg with co-existent moderate-to-severe plaque psoriasis	90 mg

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (such as documented member's BSA improvement, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member have had a documented trial and inadequate response with **ONE** of the following:
   a) 6-mercaptopurine or azathioprine;
   b) Corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
   c) 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.); AND
4. If the request is for a non-preferred ustekinumab product, member has tried and failed three (3) preferred ustekinumab products (see appendix for preferred and non-preferred products); AND
5. Must have had a negative TB test within the last 12 months.
6. **Dosage allowed/Quantity limit:**
   a) Induction (medical benefit): a one-time IV infusion based on weight.

Weight (kilograms)	Recommended Dosage

55 kg or less	260 mg (2 vials)
greater than 55 kg to 85 kg	390 mg (3 vials)
greater than 85 kg	520 mg (4 vials)

b) Maintenance (pharmacy or medical benefit): subcutaneous injection of 90 mg dose 8 weeks after induction and every 8 weeks thereafter.

Note to reviewer: A one-time induction dose is approved on the medical benefit. Maintenance therapy is approved on either pharmacy OR medical benefit. Please inactivate any duplicate prior authorization.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of UC (such as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ustekinumab (Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana, Yesintek) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/10/2017	Policy for Stelara created. Policies SRx-0042 and SRx-0043 archived. New diagnosis of Crohn's disease was added. For diagnosis of PsO: immunosuppressive criterion was separated from phototherapies and topical agents trials; TNF inhibitors Humira and Enbrel were listed as required trials; Psoriasis Area and Severity Index (PASI) score requirement was added. For diagnosis of PsA: TNF inhibitors Humira and Enbrel were listed as required trials. List of diagnoses considered not medically necessary was added.
11/13/2017	Age requirement for diagnosis of PsO updated.
02/26/2019	Humira was removed from criteria; Cimzia, Cosentyx, Otezla, Siliq and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
10/31/2019	New indication of Ulcerative Colitis added.
11/23/2020	Removed repeat TB for reauth for all diagnoses. For CD: specified length of trials for conventional therapies, previously not specified. For severe disease, removed esophageal/gastroduodenal disease, specified that history of colonic resection must also be high risk for recurrence. Updated dosage section and added note for internal PA review. For PsO: Age requirement expanded to include 6 years or older. Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. For PsA: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). For UC: removed Mayo score requirement; removed TNF as a trial option; specified the length of trials for conventional therapies (previously not specified). Updated dosage section and added note for internal PA review.

03/05/2022	Transferred to new template. Updated references. Simplified wording for TB test and DMARD requirements. Removed initial criteria requirement from reauthorization. Removed TNF trial requirement for CD.
03/17/2022	Removed preferred biologic trials.
08/19/2022	Lowered age for PsA to at least 6 years of age. Updated dosing section. Updated references.
09/26/2024	PsO: converted double trial of topicals + systemic therapy to a single trial with both topical and systemic options.
07/29/2025	Updated references. UC: Removed duration from drug trial, added guideline references. CD: removed duration from trials; replaced “biologics” with “advanced therapies (biologic, JAK inhibitor, etc.)”; added provider attestation to severe disease that requires immediate use of advanced therapy PsA and PsO: replaced “non-biologic” with “conventional”
12/10/2025	Added biosimilar PI references. Changed title of policy from “Stelara (ustekinumab)” to “Ustekinumab (Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana, Yesintek)”; added appendix table with preferred and non-preferred products; added trial of 3 preferred ustekinumab products

Preferred	Non-Preferred
• Yesintek • Steqeyma • Ustekinumab-ttwe	• Stelara • Starjemza • Imuldosa • Selarsdi • Ustekinumab-aekn • Pyzchiva • Otulfi • Ustekinumab-aauz • Wezlana

References:

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2. Imuldosa [package insert]. BioPharma Inc.; 2025.
3. Otulfi [package insert]. Fresenius Kabi USA; 2025.
4. Pyzchiva [package insert]. Sandoz Inc.; 2024.
5. Selarsdi [package insert]. Alvotech USA Inc.; 2025.
6. Starjemza [package insert]. Bio-Thera Solutions, Ltd.; 2025.
7. Steqeyma [package insert]. Celltrion Inc.; 2025.
8. Wezlana [package insert]. Amgen Inc.; 2024.
9. Yesintek [package insert]. Biocon Biologics Inc.; 2024.
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