POLICY: Inflammatory Conditions – Stelara Subcutaneous Prior Authorization Policy

- Stelara® (ustekinumab subcutaneous injection – Janssen Biotech)
- Otulfi™ (ustekinumab-aauz subcutaneous injection– Formycon/Fresenius)
- Pyzchiva™ (ustekinumab-ttwe subcutaneous injection– Sandoz/Samsung)
- Selarsdi™ (ustekinumab-aekn subcutaneous injection– Alvotech/Teva)
- Steqeyma™ (ustekinumab-stba subcutaneous injection– Celltrion)
- Wezlana™ (ustekinumab-auub subcutaneous injection– Amgen)
- Yesintek™ (ustekinumab-kfce subcutaneous injection– Biocon)

EFFECTIVE DATE: 1/1/2023
LAST REVISION DATE: 1/14/2025, selected revision 01/29/2025

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Ustekinumab subcutaneous, an interleukin-12/23 blocker, is indicated for the following uses:[1,8-13]

- **Crohn's disease**, in patients ≥ 18 years of age with moderate to severe active disease.
- **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for phototherapy or systemic therapy.
- **Psoriatic arthritis**, in patients ≥ 6 years of age with active disease.
- **Ulcerative colitis**, in patients ≥ 18 years of age with moderate to severe active disease.

Dosing

A weight-based dose is administered by subcutaneous (SC) injection under the supervision of a physician or by the patient or a caregiver. Here is the approved dosing listed in the prescribing information:

- **Crohn's disease:** Starting 8 weeks after an initial intravenous (IV) dose, the maintenance dose is 90 mg SC injection once every 8 weeks (Q8W).
- **Plaque psoriasis:**
  - Adults weighing ≤ 100 kg: 45 mg SC at Week 0, Week 4, and then once every 12 weeks (Q12W) thereafter.
  - Adults weighing > 100 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing > 100 kg: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.
    - **Psoriatic arthritis:**
  - Adults weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then every Q12W thereafter.
  - All other adults: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing < 60 kg: 0.75 mg/kg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing 60 kg to 100 kg: 45 mg SC at Week 0, Week 4, and then Q12W thereafter.
  - Pediatric patients ≥ 6 years of age weighing > 100 kg with co-existent moderate to severe plaque psoriasis: 90 mg SC at Week 0, Week 4, and then Q12W thereafter.

- **Ulcerative colitis:** Starting 8 weeks after an initial IV dose, the maintenance dose is 90 mg SC Q8W.

Guidelines
Guidelines for the treatment of inflammatory conditions recommend use of ustekinumab subcutaneous.

- **Crohn's Disease:** The American College of Gastroenterology has guidelines for Crohn's disease (2018).[2] Ustekinumab is a treatment option in patients who have moderate to severe disease despite treatment with another agent (e.g., corticosteroid, thiopurine, methotrexate, or tumor necrosis factor inhibitors [TNFis]).
- **Plaque Psoriasis:** Guidelines from the American Academy of Dermatology and National Psoriasis Foundation (2019) recommend ustekinumab as a monotherapy treatment option or in combination with other therapies for adults with moderate to severe disease.[3]
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology (2018) recommend ustekinumab after other agents (e.g., TNFis) have been tried.[4] Ustekinumab may be used in patients who have active disease despite treatment with other agents, particularly in those with concomitant inflammatory bowel disease.[4]
- **Ulcerative Colitis:** The AGA (2024) and ACG (2019) have clinical practice guidelines on the management of moderate to severe ulcerative colitis in adults.[5,6] AGA recognizes all of the FDA-approved advanced therapies as potential options for adults with moderate to severe UC.[4] Advanced therapies include the biologics and targeted synthetic small molecule drugs. In general, the AGA recommends starting with advanced therapies and/or immunomodulators. Immunomodulators are recommended in the setting of maintenance of clinical remission induced by corticosteroids. The ACG recommend TNF inhibitors, Entyvio® (vedolizumab IV infusion/subcutaneous injection), Stelara® (ustekinumab IV infusion/subcutaneous injection), or Xeljanz®/Xeljanz® XR (tofacitinib tablets, tofacitinib extended-release tablets) for induction treatment of moderate to severe disease.[5] The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.[6]

POLICY STATEMENT

Due to the information outlined in Article A53022 (Self-Administered Drug Exclusion List: Medical Policy Article) by the Centers for Medicaid and Medicare Services, the subcutaneous Ustekinumab formulations are considered self-administered products and are therefore not eligible for coverage by Medicare if administered in a healthcare setting and billed as a medical claim. Coverage may be obtained through the pharmacy benefit and billed as a Medicare Part D claim. Please note, additional prior authorization criteria may apply.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

None.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ustekinumab subcutaneous is not recommended in the following situations:

1. When administered in a healthcare setting by a healthcare professional and billed as a medical claim.

REFERENCES

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1. Stelara® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech; March 2024.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: management of Crohn's disease in adults. *Am J Gastroenterol.* 2018;113(4):481-517.
3. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
5. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
6. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
7. Poddubnyy D, Hermann KG, Callhoff J, et al. Ustekinumab for the treatment of patients with active ankylosing spondylitis: results of a 28-week, prospective, open-label, proof-of-concept study (TOPAS). *Ann Rheum Dis*. 2014;73(5):817-823.
8. Otulfi® intravenous infusion, subcutaneous injection [prescribing information]. Lake Zurich, IL: Fresenius; December 2024.
9. Pyzchiva® intravenous infusion, subcutaneous injection [prescribing information]. Princeton, NJ: Sandoz; June 2024.
10. Selarsdi® intravenous infusion, subcutaneous injection [prescribing information]. Parsippany, NJ: Teva; October 2024.
11. Steqeyma® intravenous infusion, subcutaneous injection [prescribing information]. Incheon, Republic of Korea: Celltrion; December 2024.
12. Yesintek® intravenous infusion, subcutaneous injection [prescribing information]. Cambridge, MA: Biocon; December 2024.
13. Wezlana® intravenous infusion, subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2025.
14. Centers for Medicaid and Medicare Services. (2024, December 3). *Self-Administered Drug Exclusion List: Medical Policy Article A53022*. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53022

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	UCare created new Medicare only policy based on Medicare article A53022 which excludes self-administered medication from being billed under Medicare Part B as they are a Medicare Part D covered benefit.	12/08/2022
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	12/3/2024
UCare Update	Policy name was changed to more generally list Ustekinumab Subcutaneous Products; previously policy was specific to Stelara Subcutaneous. Wezlana subcutaneous was added to the policy; the same criteria apply for Wezlana and for Stelara subcutaneous.	01/14/2025
Selected Revision	Otulfi, Pyzchiva, Selarsdi, Steqeyma, and Yesintek subcutaneous were added to the policy; the same criteria apply for all ustekinumab subcutaneous products.	01/29/2025