POLICY: Inflammatory Conditions – Tremfya Subcutaneous Prior Authorization Policy

- Tremfya® (guselkumab subcutaneous injection – Janssen Biotech/Johnson & Johnson)

EFFECTIVE DATE: 2/1/2025
LAST REVISION DATE: 12/3/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Tremfya, an interleukin (IL)-23 blocker, is indicated for the following uses:[1]

- **Plaque psoriasis**, in adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in adults with active disease (given ± a conventional synthetic disease-modifying antirheumatic drug).
- **Ulcerative colitis**, in adults with moderate to severe active disease.

Guidelines

IL blockers are mentioned in guidelines for treatment of inflammatory conditions.

- **Plaque Psoriasis:** Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.[2] These guidelines list Tremfya as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. It is recommended that a response to therapy be ascertained after 12 weeks of continuous therapy. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara® [ustekinumab subcutaneous injection]) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.[3]
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology/National Psoriasis Foundation (2018) were published prior to approval of Tremfya for psoriatic arthritis. However, these guidelines generally recommend tumor necrosis factor (TNF) inhibitors as the first-line treatment strategy over other biologics (e.g., IL-17 blockers, IL-12/23 inhibitor) with differing mechanisms of action.[4]
- **Ulcerative colitis (UC):** Current guidelines do not address the use of Tremfya for UC. The American Gastroenterological Association (2020) and the American College of Gastroenterology (2019) have clinical practice guidelines on the management of moderate to severe UC and make recommendations for the use of biologics for induction and maintenance of remission in adults.[5,6] Generally TNF inhibitors, Entyvio® (vedolizumab intravenous infusion/subcutaneous injection), Stelara® (ustekinumab

intravenous infusion/subcutaneous injection), or Xeljanz®/Xeljanz® XR (tofacitinib tablets, tofacitinib extended-release tablets), are recommended for induction treatment of moderate to severe disease (strong recommendations, moderate quality of evidence). The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

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 Tremfya subcutaneous formulation is considered a self-administered product and is 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 Tremfya 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

1. Tremfya® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson September 2024.
2. 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.
3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol*. 2015;29(12):2277-2294.
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 Rheumatol.* 2019;71(1):5-32.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.

6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020 Apr158(5):1450-1461.
7. 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	Aspirus 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 with an effective date of 1/15/25.	12/03/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	12/16/2024