DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Tremfya Subcutaneous Drug Quantity Management Policy – Per Days
- Tremfya® (guselkumab subcutaneous injection – Janssen)

REVIEW DATE: 04/09/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tremfya, an interleukin (IL)-23 blocker, is indicated for the following uses:[1]
- **Crohn's disease**, in adults with moderate to severe active disease.
- **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.

Dosing

Crohn's Disease

The initial dose of Tremfya for Crohn's disease is 200 mg intravenous (IV) infusion at Weeks 0, 4, and 8 or 400 mg subcutaneous (SC) injection (given as 2

consecutive 200 mg injections) at Weeks 0, 4, and 8.[1] Following induction, the recommended maintenance dose is:

- 100 mg SC at Week 16, then once every 8 weeks (Q8W) thereafter; OR
- 200 mg SC at Week 12, then once every 4 weeks (Q4W) thereafter.

Plaque Psoriasis and Psoriatic Arthritis
For both plaque psoriasis and psoriatic arthritis, the recommended dose is 100 mg as a SC injection at Week 0 and Week 4, then 100 mg SC once every 8 weeks thereafter.[1]

Ulcerative colitis
In ulcerative colitis, a three-dose induction regimen (200 mg at Weeks 0, 4, and 8) is administered by IV infusion.[1] Following induction therapy with the IV product, the recommended maintenance dose for Tremfya SC injection is:

- 100 mg SC at Week 16, then Q8W thereafter; OR
- 200 mg SC at Week 12, then Q4W thereafter.

Availability

Tremfya is available in the following forms:[1]

- 100 mg/mL single-dose patient-controlled injector
- 100 mg/mL single-dose prefilled syringe
- 100 mg/mL single-dose prefilled pen
- 200 mg/2 mL single-dose prefilled pen
- 200 mg/2 mL single-dose prefilled syringe
- Crohn's Disease Induction Pack: 2 x 200 mg/2 mL prefilled pens

Tremfya is also available a 200 mg/20 mL single-dose vial intended for IV administration.[1] It is not addressed in this policy.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Tremfya, and to manage potential premature dose escalation. If the Drug Quantity Management rule is not met at the point of service, coverage will be determined by the Criteria below. "One-time" overrides are provided for 30 days, unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Tremfya® (guselkumab subcutaneous injection)	100 mg/mL injector	100 mg (1 injector) per 56 days	
	100 mg/mL prefilled syringe	100 mg (1 syringe) per 56 days	
	100 mg/mL prefilled pen	100 mg (1 pen) per 56 days	
	200 mg/2 mL prefilled pen	200 mg (1 pen) per 28 days	600 mg (3 pens) per 84 days

	200 mg/2 mL prefilled syringe	200 mg (1 syringe) per 28 days	600 mg (3 syringes) per 84 days
	2 x 200 mg/2 mL prefilled pen Induction Pack for Crohn's Disease	1,200 mg (6 pens/3 Induction Packs) per 365 days	

Inflammatory Conditions – Tremfya Subcutaneous Drug Quantity Management Policy – Per Days **product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA

Tremfya 100 mg/mL prefilled syringes, patient-controlled injectors, and pens

1. If the patient is initiating treatment for plaque psoriasis or psoriatic arthritis or requires additional induction dosing for plaque psoriasis or psoriatic arthritis, as verified by the absence of claims for Tremfya in the past 130 days, approve a one-time override for 200 mg (2syringes, injectors, or pens) at retail or home delivery.

Tremfya 200 mg/2mL prefilled pens and syringes

1. If the patient is initiating treatment for Crohn's disease or requires additional induction dosing for Crohn's disease, as verified by the absence of claims for Tremfya in the past 130 days, approve a one-time override for 84 days for an additional 1,200 mg (6 pens).

Tremfya 200 mg/2 mL prefilled pens Induction Pack for Crohn's Disease

1. If the patient requires additional induction dosing for Crohn's disease, as verified by the absence of claims for Tremfya in the past 130 days, approve a one-time override for 84 days for an additional 1,200 mg (6 pens/3 Induction Packs). Note: The approval quantity should be the number of mg of Tremfya the patient has received in the past 365 days plus 1,200 mg.

REFERENCES

1. Tremfya® subcutaneous injection [prescribing information]. Horsham, PA: Janssen; March 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/03/2024
Early Annual Revision	Policy name was changed to "Inflammatory Conditions – Tremfya Subcutaneous Drug Quantity Management Policy – Per Days". Previously, the name was "Inflammatory Conditions – Tremfya Drug Quantity Management Policy – Per Days". **Tremfya 100 mg/mL patient-controlled injectors and prefilled syringes:** Override criteria were clarified to approve an additional	10/09/2024

	quantity if the patient is initiating treatment for plaque psoriasis or psoriatic arthritis or requires additional induction dosing for plaque psoriasis or psoriatic arthritis. Previously, these criteria were not indication-specific. **Tremfya 200 mg/2mL prefilled pens and syringes:** New quantity limits of 200 mg (1 pen/syringe) per 28 days at retail and 600 mg (3 pens/syringes) per 84 days at home delivery were added to the policy. No override criteria apply.	
Early Annual Revision	The Policy Statement was updated to clarify that "One-time" overrides are provided for 30 days in duration, unless otherwise noted below. **Tremfya 100 mg/mL prefilled pens:** New quantity limit of 100 mg (1 pen) per 56 days at retail and home delivery was added. Override criteria were added to approve a one-time override for 200 mg (2 pens) at retail or home delivery if the patient is initiating treatment for plaque psoriasis or psoriatic arthritis or if the patient requires additional induction dosing for plaque psoriasis or psoriatic arthritis. **Tremfya 200 mg/2mL prefilled pens and syringes:** New override criteria were added to approve a one-time override for 84 days for an additional 1,200 mg (6 pens) if the patient is initiating treatment for Crohn's disease or requires additional induction dosing for Crohn's disease, as verified by the absence of claims for Tremfya in the past 130 days. **Tremfya 200 mg/2 mL prefilled pens Induction Pack for Crohn's Disease:** New quantity limit of 1,200 mg (6 pens/3 Induction Packs) per 365 days at retail and home delivery was added. Override criteria were added to approve a one-time override for 84 days for an additional 1,200 mg (6 pens/3 Induction Packs) if the patient requires additional induction dosing for Crohn's disease, as verified by the absence of claims for Tremfya in the past 130 days.	04/09/2025