DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 10/09/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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]
- **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.

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Dosing

Plaque Psoriasis and Psoriatic Arthritis

For both plaque psoriasis and psoriatic arthritis, the recommended dose is 100 mg as a subcutaneous (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 intravenous (IV) infusion.[1] Following induction therapy with the

IV product, the recommended maintenance dose for Tremfya subcutaneous (SC) injection is:

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

The lowest effective dose is recommended to maintain a therapeutic response.

Availability

Tremfya is available in the following forms:[1]

- 100 mg/mL single-dose patient-controlled injector
- 100 mg/mL single-dose prefilled syringe
- 200 mg/2 mL single-dose prefilled pen
- 200 mg/2 mL single-dose prefilled syringe

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. All approvals are provided for the duration 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	
	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 syringes) per 28 days	600 mg (3 syringes) per 84 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 and patient-controlled injectors

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 (2 prefilled syringes or patient-controlled injectors) at retail or home delivery.

Tremfya 200 mg/2mL prefilled pens and syringes
No overrides recommended.

REFERENCES

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

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 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.	10/09/2024