DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 02/05/2026

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

Simponi subcutaneous (SC), a tumor necrosis factor inhibitor (TNFi), is approved for the following uses:[1]

- **Ankylosing spondylitis,** for treatment of adults with active disease. either alone or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
- **Psoriatic arthritis,** for treatment of adults with active disease either alone or in combination with methotrexate or other non-biologic DMARDs.
- **Rheumatoid arthritis,** for treatment of adults with moderately to severely active disease in combination with methotrexate.
- **Ulcerative colitis,** for the treatment of adults and pediatric patients weighing ≥ 15 kg with moderately to severely active disease.

Dosing

Dosage recommendations for Simponi SC are:[1]

- **Ankylosing Spondylitis, Psoriatic Arthritis, Rheumatoid Arthritis:** 50 mg once monthly.
- **Ulcerative Colitis:**
  - Adults and pediatric patients who weigh ≥ 40 kg: 200 mg initially at Week 0, followed by 100 mg at Week 2 and then 100 mg every 4 weeks (Q4W) thereafter.
  - Pediatric patients who weigh ≥ 15 kg to < 40 kg: 100 mg initially at Week 0, followed by 50 mg at Week 2 and then 50 mg Q4W thereafter.

Availability

Simponi SC is available in the following forms:[1]

- 50 mg/0.5 mL and 100 mg/mL prefilled syringes
- 50 mg/0.5 mL and 100 mg/mL prefilled SmartJect® autoinjectors

Of note, Simponi Aria® (golimumab intravenous injection) is also available as 50 mg/4 mL vials. This dose form is not targeted in this policy.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Simponi SC, 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. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Simponi® (golimumab subcutaneous injection)	50 mg/0.5 mL prefilled syringe	1 syringe/autoinjector	3 syringes/autoinjectors
	50 mg/0.5 mL prefilled SmartJect® autoinjector		
	100 mg/mL prefilled syringe	1 syringe/autoinjector	3 syringes/autoinjectors
	100 mg/mL prefilled SmartJect® autoinjector		

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Simponi SC 50 mg/0.5 mL prefilled syringes or prefilled SmartJect® autoinjectors
No overrides recommended.

Simponi SC 100 mg/mL prefilled syringes or prefilled SmartJect® autoinjectors

1. If the patient is initiating treatment for ulcerative colitis or requires additional induction dosing for ulcerative colitis, as verified by the absence of claims for Simponi in the past 130 days, approve a one-time override for 3 syringes or autoinjectors at retail or 5 syringes or autoinjectors at home delivery.
Note: This override at retail allows for initiation dosing at Week 0 and Week 2. This override at home delivery allows for initiation dosing at Week 0 and Week 2 and then 100 mg once every 4 weeks at Week 6 and Week 10.

REFERENCES

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

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/04/2024
Annual Revision	The Policy Statement was updated to clarify that "One-time" overrides are provided for 30 days in duration.	02/10/2025
Annual Revision	No criteria changes.	02/05/2026