DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 01/04/2024

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

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 moderate to severe active disease in combination with methotrexate.
- **Ulcerative colitis,** for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders in adults with moderate to severe disease who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine.

Dosing

Dosage recommendations for Simponi SC are:[1]

- **Ankylosing Spondylitis, Psoriatic Arthritis, Rheumatoid Arthritis:** 50 mg once monthly.
- **Ulcerative Colitis:** 200 mg initially at Week 0, followed by 100 mg at Week 2 and then 100 mg every 4 weeks 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 1 year in duration unless otherwise noted below.

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 prefilled syringe	3 prefilled syringes
	50 mg/0.5 mL prefilled SmartJect® autoinjector	1 autoinjector	3 autoinjectors
	100 mg/mL prefilled syringe	1 prefilled syringe	3 prefilled syringes
	100 mg/mL prefilled SmartJect® autoinjector	1 autoinjector	3 autoinjectors

Inflammatory Conditions – Simponi 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

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 prefilled syringes or autoinjectors at retail or 5 prefilled syringes 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; September 2019.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes. Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	12/19/2022
Annual Revision	No criteria changes.	01/04/2024