DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 12/19/2022

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.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail	Home Delivery

		Maximum Quantity per 28 Days	Maximum Quantity per 84 Days
Simponi® (golimumab subcutaneous injection)	50 mg prefilled syringe	1 prefilled syringe	3 prefilled syringes
	50 mg prefilled SmartJect® autoinjector	1 autoinjector	3 autoinjectors
	100 mg prefilled syringe	1 prefilled syringe	3 prefilled syringes
	100 mg prefilled SmartJect® autoinjector	1 autoinjector	3 autoinjectors

CRITERIA

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

Simponi SC 100 mg prefilled syringes or prefilled SmartJect® autoinjectors

1. If the patient is initiating treatment or requires additional induction dosing for the treatment of ulcerative colitis, as verified by the absence of claims for Simponi in the past 130 days, approve a one-time quantity of up to 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.