



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Inflammatory Conditions – Skyrizi Subcutaneous Drug Quantity Management Policy – Per Days
- Skyrizi® (risankizumab-rzaa subcutaneous injection – Abbvie)

REVIEW DATE: 01/03/2024

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

Skyrizi subcutaneous (SC), an interleukin (IL)-23 blocker, is indicated for the following uses:¹

- **Crohn's disease**, in patients with moderate to severe active disease; AND
- **Plaque psoriasis**, for treatment of adults with moderate to severe who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, for treatment of adults with active disease.

Dosing

Crohn's Disease

The recommended induction dose of Skyrizi is 600 mg administered by intravenous (IV) infusion at Week 0, Week 4, and Week 8.¹ Then, the recommended maintenance dose is 180 mg or 360 mg administered by SC injection at Week 12 and every 8 weeks thereafter. Use the lowest effective dosage needed to maintain therapeutic response.

Plaque Psoriasis and Psoriatic Arthritis

The recommended dose of Skyrizi is 150 mg, given either as two 75 mg SC injections or one 150 mg SC injection, at Week 0, Week 4, and then once every 12 weeks thereafter.¹

Availability

Skyrizi SC is available in the following forms:

- 150 mg/mL prefilled syringes (each carton contains one syringe)
- 150 mg/mL single-dose prefilled pens (each carton contains one pen)
- 180 mg/1.2 mL (150 mg/mL) single-dose prefilled cartridge with on-body injector
- 360 mg/2.4 mL (150 mg/mL) single-dose prefilled cartridge with on-body injector

Of note, Skyrizi IV administration is available as a 600 mg/10 mL (60 mg/mL) vial. However, the IV vial 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 Skyrizi 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.

Drug Quantity Limits

Product	Strength and Form	Retail and Home Delivery Maximum Quantity Per Days
Skyrizi® (risankizumab-rzaa subcutaneous injection)	150 mg/mL prefilled syringe	1 prefilled syringe per 84 days
	150 mg/mL prefilled pen	1 prefilled pen per 84 days
	180 mg/1.2 mL (150 mg/mL) prefilled cartridge	1 prefilled cartridge (1.2 mL) per 56 days
	360 mg/2.4 mL (150 mg/mL) prefilled cartridge	1 prefilled cartridge (2.4 mL) per 56 days

Inflammatory Conditions – Skyrizi 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

Skyrizi 150 mg prefilled pens and prefilled syringes

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 Skyrizi in the past 130 days, approve a one-time override for 2 prefilled pens or prefilled syringes (300 mg total) at retail or home delivery.

Skyrizi 180 mg/1.2 mL prefilled cartridge
No overrides recommended.

Skyrizi 360 mg/2.4 mL prefilled cartridge
No overrides recommended.

REFERENCES

1. Skyrizi® subcutaneous injection [prescribing information]. North Chicago, IL: AbbVie; September 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	12/15/2022
Selected Revision	180 mg/1.2 mL (150 mg/mL) prefilled cartridge: A new quantity limit was added for one 180 mg/1.2 mL prefilled cartridge per 56 days. No overrides recommended.	01/11/2023
Annual Revision	75 mg/0.83 mL prefilled syringe: The quantity limits and override criteria for the 75 mg/0.83 mL prefilled syringes were removed from the policy (product obsolete).	01/03/2024

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