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: 02/03/2025

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

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

- **Crohn's disease**, for treatment of adults with moderate to severe active disease.
- **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.
- **Ulcerative colitis**, for treatment of adults with moderate to severe 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 at Week 0, Week 4, and then once every 12 weeks thereafter.[1]

Ulcerative Colitis
The recommended induction dose of Skyrizi is 1,200 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.

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. "One-time" overrides are provided for 30 days.

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	150 mg (1 syringe) per 84 days
	150 mg/mL prefilled pen	
	180 mg/1.2 mL (150 mg/mL) prefilled cartridge	1.2 mL (1 prefilled cartridge) per 56 days
	360 mg/2.4 mL (150 mg/mL) prefilled cartridge	2.4 mL (1 prefilled cartridge) 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 300 mg (2 pens or syringes) at retail or home delivery. Note: The approval quantity is the number of mg of Skyrizi the patient has received in the past 84 days plus 300 mg at retail and 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; June 2024.

History

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	Policy statement was updated to clarify that "One-time" overrides are provided for 30 days. **Skyrizi 150 mg prefilled pens and prefilled syringes**: Override criteria were updated to reflect the override amount in "mg" instead of "number of pens/syringes". Criteria Note was added to clarify that the approval quantity is the number of mg of Skyrizi the patient has received in the past 84 days plus 300 mg at retail and home delivery.	02/03/2025