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: 12/15/2022; selected revision 01/11/2023

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:
- 75 mg/0.83 mL prefilled syringes (each carton contains two syringes)
- 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.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail and Home Delivery Maximum Quantity Per Days
Skyrizi™ (risankizumab-rzaa subcutaneous injection)	75 mg/0.83 mL prefilled syringe	2 prefilled syringes (1 kit) per 84 days
	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

CRITERIA

Skyrizi 75 mg prefilled syringes

1. If the patient is initiating treatment or requires additional induction dosing, as verified by the absence of claims for Skyrizi in the past 130 days, approve a one-time override for 4 prefilled syringes (2 kits = 300 mg total) at retail or home delivery.

Skyrizi 150 mg prefilled pens and prefilled syringes

1. If the patient is initiating treatment or requires additional induction dosing, 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.

NA – Not applicable.