# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Inflammatory Conditions – Rinvoq Drug Quantity Management Policy – Per Days
- Rinvoq® (upadacitinib extended-release tablets – AbbVie)

**REVIEW DATE:** 09/13/2023

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***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. 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

Rinvoq, a Janus kinase inhibitor (JAKi), is indicated for the following uses:[1]
- **Ankylosing spondylitis**, for treatment of active disease in adults who have had an inadequate response or intolerance to one or more tumor necrosis factor inhibitors (TNFis).
- **Atopic dermatitis**, for treatment of refractory, moderate to severe atopic dermatitis in patients ≥ 12 years of age, whose disease is not adequately controlled with other systemic drug products (including biologics) or when those therapies are not advisable.
- **Crohn's disease**, for treatment of moderately to severely active disease in adults who have had an inadequate response or intolerance to one or more TNFis.
- **Non-radiographic axial spondyloarthritis**, in adults with objective signs of inflammation who have had an inadequate response or intolerance to one or more TNFis.
- **Psoriatic arthritis**, for treatment of active disease in adults who have had an inadequate response or intolerance to one or more TNFis.

- **Rheumatoid arthritis**, for treatment of moderately to severely active disease in adults who have had an inadequate response or intolerance to one or more TNFis.
- **Ulcerative colitis**, for treatment of moderately to severely active disease in adults who have had an inadequate response or intolerance to one or more TNFis.

**Dosing**
Dosage recommendations for Rinvoq are:[1]
- **Ankylosing spondylitis**: 15 mg once daily (QD).
- **Atopic dermatitis**: 15 mg QD.
  - Patients 12 to < 65 years of age who weight ≥ 40 kg: Initiate treatment at 15 mg QD. If an adequate response is not achieved, consider increasing to 30 mg QD.
- **Crohn's disease**: 45 mg QD for 12 weeks, then 15 mg QD.
  - A dose of 30 mg QD may be considered for patients with refractory, severe, or extensive disease.
- **Non-radiographic axial spondyloarthritis**: 15 mg QD.
- **Psoriatic arthritis**: 15 mg QD.
- **Rheumatoid arthritis**: 15 mg QD.
- **Ulcerative colitis**: 45 mg QD for 8 weeks, then 15 mg QD.
  - A dose of 30 mg QD may be considered for patients with refractory, severe, or extensive disease.

**Availability**
Rinvoq is available as 15 mg and 30 mg tablets supplied in bottles containing 30 tablets each.[1] Rinvoq is also available as 45 mg tablets in bottles of 28 tablets.

**POLICY STATEMENT**
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Rinvoq. 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 Maximum Quantity | Home Delivery Maximum Quantity |
|---|---|---|---|
| Rinvoq® (upadacitinib extended-release tablets) | 15 mg tablets | 30 tablets per 30 days | 90 tablets per 90 days |
| | 30 mg tablets | 30 tablets per 30 days | 90 tablets per 90 days |
| | 45 mg tablets | 56 tablets per 365 days | 56 tablets per 365 days |

**Inflammatory Conditions – Rinvoq 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

Rinvoq 15 mg and 30 mg tablets
No exceptions.

Rinvoq 45 mg tablets

1. If the patient is initiating treatment for Crohn's disease or requires additional induction dosing for Crohn's disease, as verified by the absence of claims for Rinvoq in the past 130 days, approve a one-time exception for the requested quantity, not to exceed 84 tablets at retail or home delivery.

2. If the patient requires additional induction dosing for ulcerative colitis, as verified by the absence of claims for Rinvoq in the past 130 days, approve a one-time exception for the requested quantity not to exceed 56 tablets at retail or home delivery.

## REFERENCES

1. Rinvoq® tablets [prescribing information]. North Chicago, IL: AbbVie; June 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Early Annual Revision | Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.<br><br>**Rinvoq 45 mg tablets:** Criteria approving an additional quantity for additional induction therapy were clarified to approve an additional quantity for additional induction therapy for ulcerative colitis. | 12/19/2022 |
| Early Annual Revision | **Rinvoq 45 mg tablets:** Exception criteria were added to approve the requested quantity, not to exceed 84 tablets at retail or home delivery if the patient is initiating treatment or requires additional induction dosing for Crohn's disease. | 09/13/2023 |