DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 12/18/2024

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

Rinvoq (tablets), 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.

- **Polyarticular juvenile idiopathic arthritis (JIA)**, in patients ≥ 2 years of age with active disease who have had an inadequate response or intolerance to one or more TNFis.
  - Rinvoq LQ shares this indication with Rinvoq tablets.
- **Psoriatic arthritis**, for treatment of active disease in patients ≥ 2 years of age who have had an inadequate response or intolerance to one or more TNFis.
  - Rinvoq LQ shares this indication with Rinvoq tablets.
- **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.
  - Patients ≥ 65 years of age: 15 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.
- **Polyarticular JIA**: Dosing is based on body weight.
  - 10 kg to < 20 kg: 3 mg (3 mL oral solution) twice daily (BID)
  - 20 kg to < 30 kg: 4 mg (4 mL oral solution) BID
  - ≥ 30 kg: 6 mg (6 mL oral solution) BID or 15 mg QD (using extended-release tablets)
- **Psoriatic arthritis**:
  - Adults: 15 mg QD.
  - Pediatric patients 2 to < 18 years of age: Dosing is based on weight.
    - 10 kg to < 20 kg: 3 mg (3 mL oral solution) BID
    - 20 kg to < 30 kg: 4 mg (4 mL oral solution) BID
    - ≥ 30 kg: 6 mg (6 mL oral solution) BID or 15 mg QD (using extended-release tablets)
- **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.

Dose adjustments are recommended in certain indications to manage renal/hepatic impairment or drug interactions (Table 1).

Table 1. Rinvoq Recommended Dose Adjustments.[1]

Indication	Renal Impairment[α]	Hepatic Impairment[β]	Concomitant Strong CYP3A4 Inhibitor
Ankylosing spondylitis	No adjustment	No adjustment	No adjustment
Atopic dermatitis	15 mg QD	No adjustment	15 mg QD
Crohn's disease	30 mg QD for 12 weeks, then 15 mg QD	30 mg QD for 12 weeks, then 15 mg QD	30 mg QD for 12 weeks, then 15 mg QD
Non-radiographic axial spondyloarthritis	No adjustment	No adjustment	No adjustment
Polyarticular JIA	No adjustment	No adjustment	No adjustment
Psoriatic arthritis	No adjustment	No adjustment	No adjustment
Rheumatoid arthritis	No adjustment	No adjustment	No adjustment
Ulcerative colitis	30 mg QD for 8 weeks, then 15 mg QD	30 mg QD for 8 weeks, then 15 mg QD	30 mg QD for 8 weeks, then 15 mg QD

[α] Dose adjustment recommendations are for patients with an estimated glomerular filtration rate (eGFR) of 15 to < 30 mL/min/1.73 m^2. Use of Rinvoq is not recommended if eGFR < 15 mL/min/1.73 m^2; [β] Dose adjustment recommendations are for patients with mild to moderate hepatic impairment (Child-Pugh A or B). Use of Rinvoq is not recommended in patients with severe hepatic impairment (Child-Pugh C); CYP – Cytochrome P450; QD – Once daily; JIA – Juvenile idiopathic arthritis.

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. Rinvoq LQ is available as a 1 mg/mL oral solution supplied in a 180 mL bottle.[2] Rinvoq LQ is not substitutable with Rinvoq extended-release tablets. Changes between Rinvoq LQ oral solution and Rinvoq extended-release tablets should be made by the health care provider.

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	
Rinvoq® LQ (upadacitinib oral solution)	1 mg/mL (180 mL bottle)	360 mL (2 bottles) per 30 days	1,080 mL (6 bottles) per 90 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 overrides recommended.

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 an override for an additional 84 tablets at retail or home delivery for 84 days.
Note: The approval quantity should be the number of Rinvoq 45 mg tablets the patient has received in the past 365 days plus 84 tablets.

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 an override for an additional 56 tablets at retail or home delivery for 56 days.
Note: The approval quantity should be the number of Rinvoq 45 mg tablets the patient has received in the past 365 days plus 56 tablets.

Rinvoq LQ oral solution
No overrides recommended.

REFERENCES

1. Rinvoq® extended-release tablets and oral solution [prescribing information]. North Chicago, IL: AbbVie; April 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Rinvoq 1 mg/mL oral solution:** New quantity limit to allow 360 mL (2 bottles) per 30 days at retail or 1,080 mL(6 bottles) per 90 days at home delivery was added to the policy. No overrides apply.	07/03/2024
Early Annual Revision	**Rinvoq 45 mg tablets:** Override criteria for Crohn's disease were clarified to approve an override for an additional 84 tablets at retail or home delivery for 84 days. Previously, these criteria approved a one-time override for the requested quantity, not to exceed 84 tablets at retail or home delivery. Override criteria for ulcerative colitis were clarified to approve an override for an additional 56 tablets at retail or home delivery for 56 days. Previously, these criteria approved a one-time override for the requested quantity, not to exceed 56 tablets at retail or home delivery.	12/18/2024