



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Rinvoq	Page:	1 of 13
Effective Date:	8/1/2024	Last Review Date:	11/2023; 7/2024
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> New Jersey <input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Florida <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Florida Kids <input type="checkbox"/> Michigan <input type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Rinvoq under the patient’s prescription drug benefit.

Description:

FDA-Approved Indications

Rinvoq is indicated for:

- A. Treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- B. Adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
- C. Treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
- D. Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.
- E. Treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.
- F. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.
- G. Treatment of adult patients with moderately to severely active Crohn’s disease who have had an inadequate response or intolerance to one or more TNF blockers.
- H. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Preferred: Rinvoq Extended-Release Tablet and Rinvoq LQ Solution

Policy/Guideline:

Documentation:



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A. Rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA) and polyarticular juvenile idiopathic arthritis (pJIA)

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Atopic dermatitis

1. Initial requests:
 - i. Chart notes or medical records showing affected area(s) and affected body surface area (where applicable).
 - ii. Chart notes, medical record documentation, or claims history of prerequisite therapies, including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
2. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

C. Ulcerative colitis (UC)

1. Initial Requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

D. Crohn's disease (CD)

1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialty:

This medication must be prescribed by or in consultation with one of the following:

- A. Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis and polyarticular juvenile idiopathic arthritis: rheumatologist
- B. Psoriatic arthritis: rheumatologist or dermatologist
- C. Atopic dermatitis: dermatologist or allergist/immunologist
- D. Ulcerative colitis and Crohn's disease: gastroenterologist



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Criteria for Initial Approval:

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active rheumatoid arthritis (RA) when the member has experienced an inadequate response or intolerance to at least one tumor necrosis factor (TNF) inhibitor.
2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for moderately to severely active RA.

B. Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when the member has had an inadequate response or intolerance to at least one TNF inhibitor.
2. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active psoriatic arthritis.

C. Atopic dermatitis

1. Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when the member has experienced an inadequate response or intolerance to at least one biologic or a targeted synthetic drug in the past year.
2. Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:
 - i. Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 - ii. Member meets one of the following:
 - iii. Member has had an inadequate treatment response with one of the following in the past year:
 - a. A medium potency to super-high potency topical corticosteroid (see Appendix)
 - b. A topical calcineurin inhibitor
 - iv. The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).



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- iii. Member has had an inadequate response to treatment with a systemic drug product (e.g., oral cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) indicated for the treatment of atopic dermatitis, or use of these therapies are not advisable for the member.

D. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active UC when the member has had an inadequate response or intolerance to at least one TNF inhibitor.
2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for moderately to severely active ulcerative colitis.

E. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.
2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

F. Crohn's disease (CD)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active CD when the member has had an inadequate response or intolerance to at least one TNF inhibitor.
2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) indicated for moderately to severely active Crohn's disease.

G. Polyarticular juvenile idiopathic arthritis (pJIA)

1. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active polyarticular juvenile idiopathic arthritis when the member has had an inadequate response or intolerance to at least one TNF inhibitor.
2. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active polyarticular juvenile idiopathic arthritis.



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Continuation of Therapy:

A. Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Psoriatic arthritis

Authorization of 12 months may be granted for members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Entesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Atopic dermatitis

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

D. Ulcerative colitis (UC)



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1. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
 - i. Stool frequency
 - ii. Rectal bleeding
 - iii. Urgency of defecation
 - iv. C-reactive protein (CRP)
 - v. Fecal calprotectin (FC)
 - vi. Endoscopic appearance of the mucosa
 - vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

E. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

F. Crohn's disease (CD)

1. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.



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2. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active Crohn’s disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
 - i. Abdominal pain or tenderness
 - ii. Diarrhea
 - iii. Body weight
 - iv. Abdominal mass
 - v. Hematocrit
 - vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
 - vii. Improvement on a disease activity scoring tool (e.g., Crohn’s Disease Activity Index [CDAI] score)

G. Polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months may be granted for members 2 years of age or older (including new members) who are using the requested medication for active polyarticular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

Other Criteria:

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.



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For all indications: Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

APPENDIX

Table. Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm ²
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
Halobetasol propionate	Lotion	0.01%	
Potency	Drug	Dosage form	Strength
	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%



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Potency	Drug	Dosage form	Strength	
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%	
		Foam	0.12%	
	Desoximetasone	Cream, Ointment	0.05%	
	Diflorasone diacetate	Cream	0.05%	
	Fluocinonide	Cream, aqueous emollient	0.05%	
	Fluticasone propionate	Ointment	0.005%	
	Mometasone furoate	Ointment	0.1%	
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream, Ointment	0.5%	
		Betamethasone dipropionate	Spray	0.05%
		Clocortolone pivalate	Cream	0.1%
		Fluocinolone acetonide	Ointment	0.025%
		Flurandrenolide	Ointment	0.05%
		Hydrocortisone valerate	Ointment	0.2%
		Mometasone furoate	Cream, Lotion, Solution	0.1%
		Triamcinolone acetonide	Cream	0.1%
Ointment	0.05% and 0.1%			
Aerosol Spray	0.2 mg per 2-second spray			
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.05%	
		Betamethasone dipropionate	Lotion	0.05%
		Betamethasone valerate	Cream	0.1%
		Desonide	Ointment, Gel	0.05%
		Fluocinolone acetonide	Cream	0.025%
		Flurandrenolide	Cream, Lotion	0.05%
		Fluticasone propionate	Cream, Lotion	0.05%
		Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
		Hydrocortisone probutate	Cream	0.1%
		Hydrocortisone valerate	Cream	0.2%
		Prednicarbate	Cream (emollient), Ointment	0.1%
		Triamcinolone acetonide	Lotion	0.1%
Ointment	0.025%			
	Alclometasone dipropionate	Cream, Ointment	0.05%	



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Potency	Drug	Dosage form	Strength
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
Cream		1%	

Approval Duration and Quantity Restrictions:

Approval:

Initial Approval: atopic dermatitis: 4 months; all other indications: 12 months

Renewal Approval: 12 months

Quantity Level Limit:

Medication	FDA-recommended dosing
Rinvog (upadacitinib) 15 mg extended-release tablet	RA, AS, nr-axSpA: 15 mg once daily PsA <ul style="list-style-type: none"> Pediatric patients 2 years of age to less than 18 years of age weighing 30 kg and greater and adults: 15 mg once daily
Rinvog (upadacitinib) 30 mg extended-release tablet	pJIA <ul style="list-style-type: none"> Pediatric patients 2 years of age and older weighing 30 kg and greater: 15 mg once daily Atopic dermatitis



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Medication	FDA-recommended dosing
Rinvoq (upadacitinib) 45 mg extended-release tablet	<ul style="list-style-type: none"> Pediatric patients 12 years of age and older weighing at least 40 kg and adults less than 65 years of age: <ul style="list-style-type: none"> Initiate treatment with 15 mg once daily. A dosage of 30 mg once daily may be considered if an adequate response is not achieved. Dose adjustments: Reduce to 15 mg once daily for patients: <ul style="list-style-type: none"> 65 years of age and older With severe renal impairment (not recommended for patients with end stage renal disease) Receiving strong CYP3A4 inhibitors <p>Ulcerative colitis</p> <ul style="list-style-type: none"> Induction dose of 45 mg once daily for 8 weeks. Maintenance dose of 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease. Dose adjustments: Induction dose of 30 mg once daily for 8 weeks and maintenance dose of 15 mg once daily for patients: <ul style="list-style-type: none"> With severe renal impairment With mild to moderate hepatic impairment (Child-Pugh A or B) Receiving strong CYP3A4 inhibitors <p>Crohn's disease</p> <ul style="list-style-type: none"> Induction dose of 45 mg once daily for 12 weeks. Maintenance dose of 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease. Dose adjustments: Induction dose of 30 mg once daily for 12 weeks and maintenance dose of 15 mg once daily for patients: <ul style="list-style-type: none"> With severe renal impairment With mild to moderate hepatic impairment (Child-Pugh A or B) Receiving strong CYP3A4 inhibitors
Rinvoq (upadacitinib) LQ 1 mg/mL oral solution	<p>PsA/pJIA</p> <ul style="list-style-type: none"> Pediatric patients 2 years to less than 18 years of age weighing: <ul style="list-style-type: none"> 10 kg to less than 20 kg: 3 mg (3 mL oral solution) twice daily 20 kg to less than 30 kg: 4 mg (4 mL oral solution) twice daily 30 kg and greater: 6 mg (6 mL oral solution) twice daily

Abbreviations: RA = rheumatoid arthritis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; nr-axSpA = non-radiographic axial spondyloarthritis, pJIA: polyarticular juvenile idiopathic arthritis



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	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

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