

Coverage Policy/Guideline					
Name:	Rinvoq		Page:	1 of 16	
Effective Date	: 5/23/2025		Last Review Date:	4/2025	
		□Florida	⊠Flor	da Kids	
Applies to: 🛛 🖾 New Jersey		⊠Maryland	□Micl	nigan	
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky 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

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- 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.
- 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.
- Adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.
- Adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers.
- 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.



Coverage Policy/Guideline

Name:	Rinvoq		Page:	2 of 16
Effective Date	e: 5/23/2025		Last Review Date:	4/2025
□Illinois		□Florida	⊠Flori	ida Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micl	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

Applicable Drug List:

Preferred: Rinvoq Extended-Release Tablet and Rinvoq LQ Solution

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and polyarticular juvenile idiopathic arthritis (pJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Atopic dermatitis

Initial requests

- Chart notes or medical records showing affected area(s) and affected body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.



Coverage Policy/Guideline

Name:	Rinvoq		Page:	3 of 16
Effective Date:	5/23/2025		Last Review Date:	4/2025
□Illinois		□Florida	⊠Flori	da Kids
Applies to:	⊠New Jersey	⊠Maryland	d 🛛 🗆 🗆 🗆 🗆 🗆 🗆 d	
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

Ulcerative colitis (UC) and Crohn's disease (CD)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties

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

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

Coverage Criteria

Rheumatoid arthritis (RA)^{1-3,5,6}

- 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, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor.
- 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 (e.g., Xeljanz, Olumiant) indicated for moderately to severely active RA.

Psoriatic arthritis (PsA)^{1,7,14}

- 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.
- 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

AETNA BETTE Coverage Polic			*ae	etna™
Name:	Rinvoq		Page:	4 of 16
Effective Date:	5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flori	da Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micl	nigan
	⊠Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

targeted synthetic drug (e.g., Xeljanz, Otezla) indicated for active psoriatic arthritis.

Atopic dermatitis^{1,9,10,21}

- 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 had an inadequate response or intolerance to at least one biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Cibinqo) in the past year.
- Authorization of 4 months may be granted for treatment of moderate-tosevere atopic dermatitis in members 12 years of age or older when all of the following criteria are met:
 - 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.
 - Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past year:
 - A medium potency to super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical Janus kinase (JAK) inhibitor
 - A topical phosphodiesterase-4 (PDE-4) inhibitor
 - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
 - Member has had an inadequate response or intolerance to treatment with a biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo) indicated for the treatment of atopic dermatitis.

Ulcerative colitis (UC)¹

• Authorization of 12 months may be granted for treatment of moderately to severely active UC when the member has had an inadequate response or intolerance to at least one TNF inhibitor.



Coverage Policy/Guideline

Name:	Rinvoq		Page:	5 of 16
Effective Date	5/23/2025		Last Review Date:	4/2025
□Illinois		□Florida	⊠Flori	ida Kids
Applies to:	⊠New Jersey	⊠Maryland	nd ⊡Michigan	
	⊠Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

• Authorization of 12 months may be granted for members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,13,15}

- 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.
- 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 (e.g., Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Crohn's disease (CD)¹

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

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.
- 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.

Continuation of Therapy

Rheumatoid arthritis (RA)^{1,3,5,6}

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 RA and who

AETNA BETTEI			*ae	etna™
Coverage Polic	cy/Guideline			
Name:	Rinvoq		Page:	6 of 16
Effective Date:	5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flori	ida Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micł	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

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.

Psoriatic arthritis^{1,7,16}

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:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Atopic dermatitis^{1,8}

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 and who achieve or maintain 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).

Ulcerative colitis (UC)^{1,10-12}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all 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:

- Stool frequency
- Rectal bleeding



Coverage Policy/Guideline

Coverage reality, datacane					
Name:	Rinvoq		Page:	7 of 16	
Effective Date	: 5/23/2025		Last Review Date:	4/2025	
□Illinois		□Florida	⊠Flori	da Kids	
Applies to: 🛛 🖾 New Jersey		⊠Maryland	□Micł	nigan	
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD	

- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,13,15}

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 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:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Crohn's disease (CD)^{1,18,19}

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

Authorization of 12 months may be granted for all 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:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound

AETNA BETTE	R HEALTH®		*a e	etna™
Coverage Polic	cy/Guideline			
Name:	Rinvoq		Page:	8 of 16
Effective Date:	5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flori	da Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micł	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

 Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Polyarticular juvenile idiopathic arthritis (pJIA)^{1,20}

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:

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

Other^{1,4}

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 12 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.

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.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%

Appendix



Name:	Rinvoq		Page:	9 of 16
Effective Date	e: 5/23/2025		Last Review Date:	4/2025
		□Florida	⊠Flori	da Kids
Applies to:		⊠Maryland	□Micł	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

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

Coverage Policy/Guideline

Coverager of	log/ dalacano			
Name:	Rinvoq		Page:	10 of 16
Effective Date	e: 5/23/2025		Last Review Date:	4/2025
□ Illinois Applies to: ⊠New Jersey		□Florida	⊠Flori	ida Kids
		⊠Maryland	□Micl	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

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Potency	Drug	Dosage form	Strength
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%

Coverage Policy/Guideline

Coverage 1 of	licy/ dulactific			
Name:	Rinvoq		Page:	11 of 16
Effective Date	e: 5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flori	ida Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micl	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

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Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%



Name:	Rinvoq		Page:	12 of 16
Effective Date	: 5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flori	da Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micł	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

Potency	Drug	Dosage form	Strength
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2- second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%

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Name:	Rinvoq		Page:	13 of 16
Effective Date	: 5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flori	ida Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micł	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%





Coverage Policy/Guideline				
Name:	Rinvoq		Page:	14 of 16
Effective Date	e: 5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flor	ida Kids
Applies to:	⊠New Jersey	⊠Maryland	□Micl	nigan
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	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
Rinvoq (upadacitinib) 15 mg extended- release tablet	 RA, AS, nr-axSpA: 15 mg once daily PsA Pediatric patients 2 years of age to less than 18 years of age weighing 30 kg and greater and adults: 15 mg once daily
Rinvoq (upadacitinib) 30 mg extended- release tablet	 pJIA Pediatric patients 2 years of age and older weighing 30 kg and greater: 15 mg once daily Atopic dermatitis Pediatric patients 12 years of age and older weighing at least 40 kg and
Rinvoq (upadacitinib) 45 mg extended- release tablet	 adults less than 65 years of age: 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: 65 years of age and older With severe renal impairment (not recommended for patients with end stage renal disease) Receiving strong CYP3A4 inhibitors





Coverage Policy/Guideline

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Name:	Rinvoq		Page:	15 of 16
Effective Date:	5/23/2025		Last Review Date:	4/2025
	□Illinois	□Florida	⊠Flori	ida Kids
Applies to:	⊠New Jersey	⊠Maryland	□Michigan	
	🛛 Pennsylvania Kids	□Virginia	□Ken	tucky PRMD
Applies to:	⊠New Jersey	⊠Maryland	□Micł	nigan

Medication	FDA-recommended dosing	
	 Induction dose of 45 mg once daily for 8 weeks. Maintenance dose of 15 mg once daily. A dosage of 30 mg once dail may be considered for patients with refractory, severe or extensive disease. Dose adjustments: Induction dose of 30 mg once daily for 8 weeks a maintenance dose of 15 mg once daily for patients: With severe renal impairment With mild to moderate hepatic impairment (Child-Pugh A or B) Receiving strong CYP3A4 inhibitors 	
	 Crohn's disease 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: 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	 PsA/pJIA Pediatric patients 2 years to less than 18 years of age weighing: 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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Name:	Rinvoq		Page:	16 of 16
Effective Date: 5/23/2025		Last Review Date:	4/2025	
	□Illinois	□Florida	⊠Florida Kids	
Applies to:	⊠New Jersey	⊠Maryland	□Michigan	
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