Rinvoq

I. 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 (e.g., Xeljanz, Olumiant) 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 experienced 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 (e.g., Xeljanz, Otezla) indicated for active psoriatic arthritis.

C. Atopic dermatitis

Authorization of up to 6 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:

1. Member has a confirmed diagnosis of moderate to severe atopic dermatitis supported by the submitted medical records; **AND**
2. Member has chronic or relapsing history that has been present for at least 6 months; **AND**
3. Individual has a history of pruritus associated with atopic dermatitis; **AND**
4. Individual has at least one of the following:

    a. Early age of onset (≤5 years of age); **OR**
    b. Atropy; **OR**
    c. Family history; **OR**
    d. Xerosis; **AND**

5. Individual has involvement of > 10% body surface area OR crucial body areas (e.g., hands, face, etc) **AND**
6. Individual must have documentation of the following :

    a. For children: facial, neck or extensor involvement; **OR**
    b. For any age group: current or previous flexural lesions; sparing of groin and axillary regions; AND

7. Individual has a skin biopsy consistent with the diagnosis of atopic dermatitis **OR** documentation is provided that other skin conditions have been excluded or adequately treated (such as scabies, seborrheic dermatitis, contact dermatitis (irritant or allergic), ichthyoses, cutaneous T-cell lymphoma, psoriasis, photosensitivity dermatoses, immune deficiency disease, and erythroderma of other causes) **AND**
8. The drug is authorized and managed by a physician with expertise in the treatment of atopic dermatitis (e.g., allergist/immunologist or dermatologist) **AND**
9. Topical therapy failure. The patient has either failed a trial, proved intolerant of a medication, or has contraindications to both below topical treatments (in accordance with AAD Guidelines:

    a. A topical calcineurin inhibitor [i.e., pimecrolimus (Elidel) or tacrolimus (Protopic)] with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks; **AND**
    b. A topical corticosteroid with an inadequate response to maintenance therapy that includes intermittent use (at least 2 days per week) for at least 12 weeks of a moderate-to-high-potency topical corticosteroid, unless involvement is limited to the face and intertriginous areas in which a lower-potency corticosteroid may be used; **AND**

10. Member has had an inadequate response to treatment with a systemic drug product (e.g., oral cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) or a biologic (e.g., Dupixent, Adbry) indicated for the treatment of atopic dermatitis, or use of these therapies are not advisable for the member.
11. The drug will NOT be used in combination with another janus kinase (JAK) inhibitor or biologic agent for the treatment of atopic dermatitis [e.g., omalizumab (e.g., Xolair), mepolizumab (e.g., Nucala), reslizumab (e.g., Cinqair), tralokinumab (e.g., Adbry) and rituximab (e.g., Rituxan)] for another atopic condition; **AND**
12. Individual has an Investigator's Global Assessment (IGA) score $\geq$ 3; **AND**

13. Individual has at least one of the following:

    a. Eczema Area and Severity Index (EASI) score $\geq$21; **OR**
    b. Weekly-average baseline worst itch score (Peak, Pruritus Numerical Rating Scale [NRS]) $\geq$4; **AND**

14. Must be dosed in accordance with the FDA label.

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 (e.g., Xeljanz) 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 (e.g., Xeljanz) 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.

II. 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 RA 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. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Atopic dermatitis

Continued approval for up to 1 year:

Requirement of documentation in the medical records that the member has achieved and maintains a clinically meaningful benefit as defined below:

1. Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting); **AND**
2. Reduction in the frequency or intensity of pruritus associated with atopic dermatitis; **AND**
3. Reduction in the frequency of disease exacerbations/flairs; **AND**
4. Reduction in the amount of Body Surface Area involvement relative to pretreatment baseline; **AND**
5. Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.);
   AND
6. Must be dosed in accordance with the FDA label.

D. Ulcerative colitis (UC)

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. 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., 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 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.

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

III. OTHER

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.

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.

IV. 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%

Potency	Drug	Dosage form	Strength
		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**
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	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%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	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

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	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%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	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%