CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Rinvoq, Rinvoq LQ (upadacitinib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Rinvoq was initially approved by the FDA in 2019 for rheumatoid arthritis. Since then, it has obtained approval for the treatment of moderate to severe atopic dermatitis, psoriatic arthritis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and polyarticular juvenile idiopathic arthritis. Rinvoq is a Janus kinase (JAK) inhibitor. It works by inhibiting the activity of one or more of the Janus kinase family of enzymes, thereby interfering with the JAK-STAT signaling pathway.

Rinvoq (upadacitinib) will be considered for coverage when the following criteria are met:

Rheumatoid Arthritis (RA)

For **initial** authorization:

1. Member is at least at least 18 years of age; AND
2. Rinvoq must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Member has documentation of an inadequate response or intolerance to **ONE** tumor necrosis factor (TNF) inhibitor (ex. Humira, Remicade, etc.); AND
6. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm3), lymphopenia (ALC <500 cells/mm3), or anemia (hemoglobin < 8 g/dL); AND
7. Member has had or will have completed a tuberculosis test within 12 months prior to starting therapy.
8. **Dosage allowed/Quantity limit:** 15 mg orally once daily. Quantity limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms such as fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:

1. Member must be 2 years of age or older and weigh at least 10 kg; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND

4. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose **AND** a 3-month trial of a non-conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
   a) Non-conventional DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-conventional DMARD are **NOT** required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has tried and failed **TWO** preferred biologic DMARDs for at least 3 months each, one of which must be a TNF inhibitor (ex. Humira, Remicade, etc.); AND
6. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (hemoglobin < 8 g/dL); AND
7. Member has had or will have completed a tuberculosis test within 12 months prior to starting therapy.
8. **Dosage allowed/Quantity limit:**
   a) Adults: 15 mg orally once daily. Quantity limit: 30 tablets per 30 days.
   b) Pediatrics: see table below.

Patient Weight	RINVOQ LQ	RINVOQ
10 kg to less than 20 kg	3 mg (3 mL oral solution) twice daily	Not recommended
20 kg to less than 30 kg	4 mg (4 mL oral solution) twice daily	Not recommended
30 kg and greater	6 mg (6 mL oral solution) twice daily	15 mg (one 15 mg tablet) once daily

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling and pain, improved skin appearance and improved quality of life.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Atopic Dermatitis (AD)

For **initial** authorization:

1. Member must be 12 years of age or older and weigh at least 40 kg; AND
2. Medication must be prescribed by a dermatologist, allergist, or immunologist; AND
3. Member has a documented diagnosis of moderate-to-severe atopic dermatitis; AND
4. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND
5. Member has a documented trial and failure to **ONE** of the following:
   a) **TWO** trials of medium to very high potency topical corticosteroids for 2 weeks;
   Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.
   b) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both or UV-B1 (narrow-band UV-B)) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks;
   Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.

c) **ONE** 12-week trial of an oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine) AND **ONE** trial of medium to very high potency topical corticosteroids for 2 weeks. *Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) for 6 weeks, Eucrisa for 4 weeks or Opzelura for 8 weeks may also be acceptable.*

6. Member has documentation of a trial and failure of, intolerance, or contraindication to Dupixent or Adbry. Treatment failure requires at least 12 weeks of therapy; AND
7. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (hemoglobin < 8 g/dL); AND
8. Member has had or will have completed a tuberculosis test within 12 months prior to starting therapy.
9. **Dosage allowed/Quantity limit:** Quantity limit: 30 tablets per 30 days.
   a) 12 years of age and older weighing at least 40 kg and adults less than 65 years of age: 15 mg orally once daily. If an adequate response is not achieved, the dosage may be increased to 30 mg orally once daily.
   b) 65 years of age and older: 15 mg orally once daily.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares, less itching/erythema, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For **initial** authorization:
1. Member is 18 years of age or older with moderately to severely active UC; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member must have a documented history of inadequate response or intolerance to a TNF inhibitor (ex. Remicade, Humira, Simponi, etc.); AND
4. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (Hg < 8 g/dL); AND
5. Member has had or will have completed a tuberculosis test within 12 months prior to starting therapy.
6. **Dosage allowed/Quantity limit:**
   a) Induction: 45 mg orally once daily for 8 weeks.
   b) Maintenance: 15 mg orally once daily. A dosage of 30 mg orally once daily may be considered for patients with refractory, severe or extensive disease. Quantity limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of UC such as clinical remission, decrease in rectal bleeding, improved endoscopic healing, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ankylosing Spondylitis (AS) or Non-radiographic Axial Spondyloarthritis (nr-AxSpA)

Note: Diagnosis of axial spondyloarthritis (axSpA) is also accepted. AxSpA consists of 2 subtypes - ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active AS, nr-axSpA or axSpA; AND
4. Member shows **ONE** of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has had a 3-month trial and failure of **ONE** preferred TNF inhibitor; AND
7. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (Hg < 8 g/dL); AND
8. Member has had or will have completed a tuberculosis test within 12 months prior to starting therapy.
9. **Dosage allowed/Quantity limit:** 15 mg once daily. Quantity limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as improvement of back pain, function, morning stiffness, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Crohn's Disease (CD)

For **initial** authorization:
1. Member is 18 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member must have a documented history of inadequate response or intolerance to a TNF inhibitor (ex. Remicade, Humira, etc.); AND
4. Member does not have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (Hg < 8 g/dL); AND
5. Member has had or will have completed a tuberculosis test within 12 months prior to starting therapy.
6. **Dosage allowed/Quantity limit:**
   a. Induction: 45 mg orally once daily for 12 weeks.
   b. Maintenance: 15 mg orally once daily. A dosage of 30 mg orally once daily may be considered for patients with refractory, severe or extensive disease. Quantity limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of CD such as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For **initial** authorization:

1. Member is 2 years of age or older; AND
2. Member has a documented diagnosis of active pJIA; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member has had an 8-week trial and failure of a non-biologic DMARD (e.g., methotrexate, leflunomide, etc.); AND
5. Member must have a documented history of inadequate response or intolerance to a tumor necrosis factor (TNF) blocker (ex. Humira, Enbrel etc); AND
6. Member does **NOT** have any laboratory abnormalities indicating neutropenia (ANC <1000 cells/mm^3), lymphopenia (ALC <500 cells/mm^3), or anemia (Hg < 8 g/dL); AND
7. Member has had or will have completed a tuberculosis test within 12 months prior to starting therapy.
8. **Dosage allowed/Quantity limit:** see table below.

Patient Weight	RINVOQ LQ	RINVOQ
10 kg to less than 20 kg	3 mg (3 mL oral solution) twice daily	Not recommended
20 kg to less than 30 kg	4 mg (4 mL oral solution) twice daily	Not recommended
30 kg and greater	6 mg (6 mL oral solution) twice daily	15 mg (one 15 mg tablet) once daily

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms such as decreased joint swelling, decreased pain and improved quality of life.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Rinvoq (upadacitinib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/26/2019	New policy for Rinvoq created.
11/19/2020	Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. Removed repeated TB test in reauth. Replaced the list of excluded diagnoses with the generic statement. Updated references.
12/30/2021	Transferred to new template. RA: Updated references. Changed initial approval duration to 6 months (was 12 months). Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1. Added trial and failure of TNF blocker; now 2nd line per label change. Added criteria for new indication of PsA. Added criteria for new indication of AD.
05/24/2022	Added criteria for new indication of UC. Added criteria for new indication of AS.
02/23/2022	Updated references. Added criteria for new indication of nr-AxSpA. Added trial duration for biologics in AD. Simplified AD header to exclude moderate to severe.

06/15/2023	Added criteria for new indication of CD.
11/20/2023	Changed trials to two topicals, one topical and phototherapy or one immunomodulator and one topical; changed duration of steroid topicals to 2 weeks, added duration of 6 weeks for TCI, 4 weeks for Eucrisa; added option of Opzelura for 8 weeks duration; changed steroid requirement from high to very high; added reference
07/31/2024	Added/removed references; simplified TB test requirement to confirm member has been or will be tested in the past 12 months prior to starting therapy; added criteria for new pJIA indication. PsA: decreased age limit from 18 years of age to 2 years of age and added that member must be 10 kg or more; edited the terminology "non-biologic" DMARD to "conventional" DMARD; added examples of improvement in reauthorization criteria. AD: added tuberculosis test requirement; added dosing note about members over 65 years of older; specified members must be at least 40 kg. UC: clarified dosing.

References:

1. Rinvoq [prescribing information]. North Chicago, IL: AbbVie Inc.; May 2024.
2. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. Ann Rheum Dis. 2020;79(6):685-699.
3. ClinicalTrials.gov. Identifier: NCT02706951. A Study Comparing Upadacitinib (ABT-494) Monotherapy to Methotrexate (MTX) Monotherapy in Subjects With Rheumatoid Arthritis (RA) Who Have an Inadequate Response to MTX (SELECT-MONOTHERAPY). Available at: https://clinicaltrials.gov/ct2/show/NCT02706951?term=NCT02706951&rank=1.
4. ClinicalTrials.gov. Identifier: NCT02675426. A Study Comparing Upadacitinib (ABT-494) to Placebo in Subjects With Rheumatoid Arthritis on a Stable Dose of Conventional Synthetic Disease-Modifying Antirheumatic Drugs (csDMARDs) Who Have an Inadequate Response to csDMARDs Alone (SELECT-NEXT). Available at: https://clinicaltrials.gov/ct2/show/NCT02675426?term=NCT02675426&rank=1.
5. ClinicalTrials.gov. Identifier: NCT02706847. A Study to Compare Upadacitinib (ABT-494) to Placebo in Subjects With Rheumatoid Arthritis on Stable Dose of Conventional Synthetic Disease-Modifying Antirheumatic Drugs (csDMARDs) Who Have an Inadequate Response or Intolerance to Biologic DMARDs (SELECT-BEYOND). Available at: https://clinicaltrials.gov/ct2/show/NCT02706847?term=NCT02706847&rank=1.
6. Van Vollenhoven R, Takeuchi T, Pangan AL, et al. Efficacy and Safety of Upadacitinib Monotherapy in Methotrexate-Naive Patients With Moderately-to-Severely Active Rheumatoid Arthritis (SELECT-EARLY): A Multicenter, Multi-Country, Randomized, Double-Blind, Active Comparator-Controlled Trial. *Arthritis Rheumatol*. 2020;72(10):1607-1620. doi:10.1002/art.41384.
7. Fleischmann RM, Genovese MC, Enejosa JV, et al. Safety and effectiveness of upadacitinib or adalimumab plus methotrexate in patients with rheumatoid arthritis over 48 weeks with switch to alternate therapy in patients with insufficient response. *Ann Rheum Dis*. 2019;78(11):1454-1462. doi:10.1136/annrheumdis-2019-215764
8. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123. doi:10.1002/art.41752
9. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. Arthritis Rheumatol. 2016 May;68(5):1060-71.
10. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021 [published correction appears in Nat Rev Rheumatol. 2022 Dec;18(12):734. doi: 10.1038/s41584-022-00861-w]. *Nat Rev Rheumatol.* 2022;18(8):465-479. doi:10.1038/s41584-022-00798-0
11. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis*. 2024;83(6):706-719. Published 2024 May 15. doi:10.1136/ard-2024-225531
12. Atopic dermatitis clinical guideline (2021). In American Academy of Dermatology. Retrieved from Atopic dermatitis clinical guideline (aad.org).
13. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132.

14. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.
15. Deleanu D, Nedelea I. Biological therapies for atopic dermatitis: An update. Exp Ther Med. 2019;17(2):1061-1067.
16. Wollenberg A, Kinberger M, Arents B, et al. European guideline (EuroGuiDerm) on atopic eczema: part I - systemic therapy. *J Eur Acad Dermatol Venereol.* 2022;36(9):1409-1431. doi:10.1111/jdv.18345
17. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care Res (Hoboken). 2019;71(10):1285-1299. doi:10.1002/acr.24025
18. Akgul O, Ozgocmen S. Classification criteria for spondyloarthropathies. World J Orthop. 2011;2(12):107-115. doi:10.5312/wjo.v2.i12.07.
19. Yu DT, Tubergen AV. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc.
20. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis. 2023;82(1):19-34. doi:10.1136/ard-2022-223296
21. Boguniewicz M, Alexis AF, Beck LA, et al. Expert Perspectives on Management of Moderate-to-Severe Atopic Dermatitis: A Multidisciplinary Consensus Addressing Current and Emerging Therapies. J Allergy Clin Immunol Pract. 2017;5(6):1519-1531. doi:10.1016/j.jaip.2017.08.005
22. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.
23. ClinicalTrials.gov. Identifier: NCT03345823. A Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Participants With Crohn's Disease Who Completed the Studies M14-431 or M14-433. Available at: https://clinicaltrials.gov/ct2/show/NCT03345823.
24. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guidelines for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res (Hoboken).* 2019 Jun;71(6):717-734.
25. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569. doi:10.1002/art.420

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