ConnectiCare

Commercial/Healthcare Exchange PA Criteria

Effective: October 18th, 2019

Prior Authorization: Rinvoq

Products Affected: Rinvoq (upadacitinib) extended-release oral tablets

Medication Description: Rinvoq is a Janus kinase inhibitor (JAKi). JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression, inhibiting JAKs reduces inflammation.

Covered Uses:

1. Rheumatoid arthritis: treatment of adults with moderate to severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers**.**
2. Psoriatic arthritis: treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
3. Atopic Dermatitis: Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis
4. Ulcerative colitis: Treatment of moderately to severely active ulcerative colitis in adults who have had an inadequate response or intolerance to 1 or more TNF blockers.
5. 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 (TNFs).
6. Non-radiographic Axial Spondyloarthritis: treatment of adults with active non-radiographic axial spondylarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

Exclusion Criteria: Concomitant use with other JAK inhibitors, biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine. Concurrent use with an anti-interleuin monoclonal antibody or use with Xolair. Active COVID-19 (coronavirus disease 2019).

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

Rheumatoid Arthritis:18 years of age and older
Psoriatic Arthritis: 18 years of age or older
Atopic Dermatitis: 12 years of age and older
Ulcerative Colitis: 18 years of age or older
Ankylosing Spondylitis: 18 years of age and older
Non-radiographic Axial Spondyloarthritis: 18 years of age and older

Prescriber Restrictions:

1. Rheumatoid arthritis: prescribed by, or in consultation, with a rheumatologist
2. Psoriatic arthritis: prescribed by, or in consultation, with a rheumatologist
3. Atopic Dermatitis: prescribed by, or in consultation with a dermatologist
4. Ulcerative Colitis: prescribed by, or in consultation, with a gastroenterologist
5. Ankylosing Spondylitis: prescribed by, or in consultation with a rheumatologist

6. Non-radiographic Axial Spondyloarthritis: prescribed by or in consultation with a rheumatologist.

Coverage Duration:
Initial: 3 months
Continuation: 3 years

Other Criteria:

Initiation

Rheumatoid Arthritis

1. Patient has a diagnosis of moderate to severe active rheumatoid arthritis and has had an inadequate response or intolerance to one or more of the following TNF blockers (A **OR** B):
   A. Patient has had inadequate response or intolerance to Enbrel **OR**
   B. Patient has had inadequate response or intolerance to Humira **AND**
   Note: Members who have had a previous trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Enbrel or Humira
2. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
3. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine).

Psoriatic Arthritis

1. Patient has a diagnosis of active Psoriatic Arthritis and has had an inadequate response or intolerance to one or more of the following TNF blockers (A **OR** B):
   A. Patient has had inadequate response or intolerance to Enbrel **OR**
   B. Patient has had inadequate response or intolerance to Humira **AND**
   Note: Members who have had a previous trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Enbrel or Humira
2. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
3. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine).

Atopic Dermatitis

1. Patient has moderate to severe atopic dermatitis and meets the following criteria (A, B, **and** C):
   A. Patient weighs at least 40kg **AND**
   B. Patient meets ONE of the following (i **or** ii):
      i. Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area according to the prescriber and meets **ALL** of the following criteria (a, b, **and** c):
         a. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; **AND**
         b. This topical corticosteroid was applied daily for at least 28 consecutive days; **AND**
         c. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; **OR**
      ii. Patient has atopic dermatitis involvement estimated to be < 10% of the body surface area according to the prescriber and meets **ALL** of the following criteria (a, b, c, **and** d):

a. Patient has atopic dermatitis affecting ONLY the following areas: face, eyes/eyelids, skin folds, and/or genitalia; **AND**
b. Patient has tried tacrolimus ointment; **AND**
c. Tacrolimus ointment was applied daily for at least 28 consecutive days; **AND**
d. Inadequate efficacy was demonstrated with tacrolimus ointment, according to the prescriber; **AND**

C. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

Ulcerative Colitis

1. Prescribed by or in consultation with a gastroenterologist; **AND**
2. Patient has clinically diagnosed ulcerative colitis; **AND**
3. Patient has had an inadequate response to other immunosuppressants, such as corticosteroids, azathioprine, and 6-mercaptopurine; **AND**
4. Patient has documented failure of, or intolerance to Humira
   Note: Members who have had a previous trial of an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Humira.

Ankylosing Spondylitis

1. Patient has clinically diagnosed Ankylosing spondylitis an inadequate response or intolerance to one or more of the following TNF blockers (A **OR** B)
   A. Patient has had inadequate response or intolerance to a 3-month trial Humira **OR**
   B. Patient has had inadequate response or intolerance to a 3-month trial to Enbrel **AND**
   Note: Members who have had a previous trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step through Humira/Enbrel
2. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
3. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine).

Non-Radiographic Axial Spondyloarthritis

1. Patient has active non-radiographic axial spondylarthritis with objective signs of inflammation who meets the following criteria (A **AND** B)
   A. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
   B. Patient has had an inadequate response or intolerance to a 3-month trial of Cimzia;
   Note: Conventional synthetic disease-modifying antirheumatic drugs (DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.

Continuation

1. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Rinvoq as evidenced by low disease activity or improvement in signs and symptoms of the condition.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Rinvoq over methotrexate.

References:

1. Product Information: Rinvoq™ tablets. North Chicago, IL: AbbVie, Inc.; January 2022.
2. Product Information: RINVOQ(TM) oral extended-release tablets, upadacitinib oral extended-release tablets. AbbVie Inc (per FDA), North Chicago, IL, 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/9/2019
2	Policy Update	Added new indication Atopic Dermatitis to match FDA Label under covered uses "Atopic Dermatitis: Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis" Added age restriction to include Atopic Dermatitis "Atopic Dermatitis: 12 years of age and older" Added prescriber restriction to include atopic dermatitis "Atopic Dermatitis: prescribed by, or in consultation with a dermatologist" Added criteria for atopic dermatitis to include 1.Patient has moderate to severe atopic dermatitis and meets the following criteria (A, B, and C): Patient weighs at least 40kg AND Patient meets ONE of the following (i or ii): i.Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area according to the prescriber and meets ALL of the following criteria (a, b, and c): a.Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND b.This topical corticosteroid was applied daily for at least 28 consecutive days; AND c.inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; OR ii.Patient has atopic dermatitis involvement estimated to be < 10% of the body surface area according to the prescriber and meets ALL of the following criteria (a, b, c, and d): a.Patient has atopic dermatitis affecting ONLY the following areas: face, yes/eyelids, skin folds, and/or genitalia; AND b.Patient has tried tacrolimus ointment; AND Tacrolimus ointment was applied daily for at least 28 consecutive days; AND d.Inadequate efficacy was demonstrated with tacrolimus ointment, according to the prescriber; AND C The	Covered Uses Age Restriction Prescriber Restrictions Other Criteria	2/03/2022

3	Policy Update	Added new indication Psoriatic Arthritis to match FDA label under covered uses "Psoriatic arthritis: treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers." Under covered uses Added age restriction "Psoriatic Arthritis: 18 years of age or older" Added prescriber restriction "Psoriatic arthritis: prescribed by, or in consultation, with a rheumatologist" Added other criteria "Psoriatic Arthritis 1.Patient has clinically diagnosed Psoriatic Arthritis and has had an inadequate response or intolerance to one or more of the following TNF blockers (A OR B):AND 2. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; AND 3. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine).	Covered Uses Age Restriction Prescriber Restrictions Other Criteria	2/03/2022
4	Update	Updated covered uses under rheumatoid arthritis to match FDA label "Rheumatoid arthritis: treatment of adults with moderate to severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers" Added criteria to Rheumatoid Arthritis to match FDA Label "Patient has documented failure or intolerance to an adequate trial of one or more TNF inhibitors (A OR B): A. Patient has had inadequate response or intolerance to Enbrel OR B. Patient has had inadequate response or intolerance to Humira" Removed "patient meets all initial authorization criteria" from continuation criteria	Covered Uses Other Criteria Continuation Criteria	2/03/2022

5	Policy Update	Added new indication of Ulcerative Colitis to covered uses, age restriction, prescriber restriction and other criteria Added note to criteria depending on indication: Note: Members who have had a previous trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Enbrel or Humira Or Note: Members who have had a previous trial of an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Humira.	Covered uses Age restriction Prescriber Restriction Other Criteria	4/1/2022
6	Policy Update	Added new indication of Ankylosing Spondylitis to covered uses, age restriction, prescriber restriction and other criteria Added note to criteria depending on indication: Note: Members who have had a previous trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) do not need to step thru Enbrel or Humira	Covered uses Age restriction Prescriber Restriction Other criteria	5/20/2022
7	Policy Update	Added new indication of **Non-Radiographic Axial Spondyloarthritis** to covered uses, age restriction, prescriber restriction and other criteria	Covered uses Age restriction Prescriber Restriction Other criteria	11/2022