Clinical Policy Title:	upadacitinib
Policy Number:	RxA.745
Drug(s) Applied:	Rinvoq®, Rinvoq LQ®
Original Policy Date:	04/18/2022
Last Review Date:	08/26/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of Rheumatoid Arthritis (RA);
2. Request is for Rinvoq tablets;
3. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate, sulfasalazine, leflunomide, hydroxychloroquine), unless contraindicated or clinically significant adverse effects are experienced;
4. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), Cimzia, Enbrel, or Simponi/Simponi Aria.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA;
2. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), Cimzia, Enbrel, or Simponi/Simponi Aria.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Atopic Dermatitis (must meet all):

1. Diagnosis of refractory, moderate to severe atopic dermatitis;
2. Request is for Rinvoq tablets;
3. Trial and failure of the following (a and b):
   a. One medium to high potency topical corticosteroid or topical calcineurin inhibitor;
   b. One systemic agent (e.g., Adbry or Dupixent).

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Ulcerative colitis (must meet all):

1. Diagnosis of ulcerative colitis;
2. Request is for Rinvoq tablets;
3. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-

mercaptopurine, aminosalicylate), unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects experienced;
4. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), or Simponi (*Simponi Aria not approved for UC).

Approval Duration
All Lines of Business (except Medicare): 12 months

E. Axial Spondylarthritis (must meet all):
1. Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondylarthritis (nr-axSpA);
2. Request is for Rinvoq tablets;
3. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs), each used for at ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
4. Inadequate response or intolerance to one preferred TNF inhibitor: (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), Cimzia, Enbrel, or Simponi/Simponi Aria.

Approval Duration
All Lines of Business (except Medicare): 12 months

F. Crohn's Disease (must meet all):
1. Diagnosis of CD;
2. Request is for Rinvoq tablets;
3. Member meets one of the following (a or b):
   a. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]), unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced;
4. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), or Cimzia.

Approval Duration
All Lines of Business (except Medicare): 12 months

G. Polyarticular Juvenile Idiopathic Arthritis (must meet all):
1. Diagnosis of polyarticular juvenile idiopathic arthritis (JIA);
2. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate or leflunomide), unless contraindicated or clinically significant adverse effects are experienced;
3. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), Simponi Aria, or Enbrel.

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021;73(7):924-939. Accessed August 26, 2024.
2. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatology. 2019;71(1):5-32. Accessed August 26, 2024.
3. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma, and Immunology. Accessed August 26, 2024.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158(5):1450-1461. Accessed August 26, 2024.
5. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. Accessed August 26, 2024.
6. 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 Rheumatol. 2019;71(10):1599-1613. Accessed August 26, 2024.
7. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis (nih.gov). Accessed August 26, 2024.
8. Rinvoq. Package insert. AbbVie. 2024. Accessed August 26, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologics_DMARDs.	02/16/2022	04/18/2022
Drug specific policy for Inflectra was created based on RxA.592.Biologics_DMARDs: 1. Initial Approval Criteria, I.A.6: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 15 mg (one tablet) per day. 2. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Psoriatic Arthritis. 3. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Atopic Dermatitis. 4. Continued Therapy Approval, II.A.3: Updated to include new dosing criteria for indication PsA & RA. 5. References were reviewed and updated.	02/16/2022	4/18/2022

Policy was reviewed: 1. Initial Approval Criteria, I.C.4: Updated to include new diagnostic criteria Member has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) and baseline scoring atopic dermatitis (SCORAD) of at least 25. 2. Initial Approval Criteria, I.C.5: Updated trial and failure criteria from Member meets one of the following (a or b); a. Trial and failure of at least one (1) systemic agent (e.g. corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; b. Trial and failure of Dupixent at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;*Exception: If one biologic DMARD that is FDA approved for atopic dermatitis has been previously tried (e.g, Dupixent, Adbry) , then trial of a systemic agent is not required to Member meets (a and b); a. Trial and failure of any two of the following: medium to high potency topical corticosteroid, pimecrolimus cream, tacrolimus topical ointment, or Eucrisa (crisaborole) ointment at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; b. Trial and failure of at least one (1) systemic agent (e.g. corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, Dupixent, Adbry) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced; 3. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Ulcerative colitis. 4. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Ankylosing Spondylitis.	04/28/2022	07/18/2022

5. Continued Therapy Approval, II.A.3.a: Updated to include new dosing criteria new indication Ankylosing Spondylitis. 6. Continued Therapy Approval, II.A.3.c: Updated to include new dosing criteria If request is for a dose increase, new dose does not exceed one of the following (a, b or c):c. IC (i or ii): i. Induction: 45 mg/day orally; ii. Maintenance treatment: 30 mg/day orally. 7. Continued Therapy Approval, II.A.3.a: Updated to include new dosing criteria new indication Ankylosing Spondylitis. 8. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.E.: Updated from Ankylosing Spondylitis to Axial Spondyloarthritis. 2. Initial Approval Criteria, I.E.1: Updated diagnostic criteria from Diagnosis of active ankylosing spondylitis (AS) to Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA). 3. Initial Approval Criteria I.E.5: Updated to remove Trial and failure of at least one (1) of the following: Humira®, Cimzia®, Enbrel®, Simponi®/Simponi Aria®, unless contraindicated or clinically significant adverse effects are experienced. 4. Continued Therapy Approval, II.A.3.a: Updated dosing criteria to include new indication nr-axSpA. 5. Initial Approval Criteria, I.A.5 and I.B.4: Updated trial and failure criteria from Trial and failure of a ≥ 3 months of at least one (1) TNF inhibitor (Cimzia®, Humira®, Simponi®/ Simponi Aria, Enbrel®), unless contraindicated or clinically significant affects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 6. Initial Approval Criteria, I.D.5: Updated trial and failure criteria from Trial and failure of at least one (1) of the following agents: Humira®, Simponi®, unless contraindicated or clinically significant adverse effects are experienced to Member should have inadequate response or intolerance to one or more TNF inhibitors. 7. References were reviewed and updated.	11/18/2022	01/17/2023

Policy was reviewed: 1. Initial Approval Criteria, I.F: Updated to include approval criteria for indication, Crohn's disease (CD). 2. Continued Therapy Approval Criteria, II.A.3.d: Updated to include new dosing criteria for indication CD. 3. References were reviewed and updated.	06/27/2023	07/13/2023
Policy was reviewed: 1. Clinical Policy Title, Lines of Business Policy Applies to: Updated from All line of Business to All lines of business (except Medicare). 2. Initial and Continued Therapy criteria updated to remove age and dose criteria. 3. Initial Approval Criteria I.C.5.a: Updated trial and failure of any two agents to trial and failure of any one. 4. References were reviewed and updated.	08/18/2023	08/25/2023
Policy was reviewed.	11/28/2023	11/28/2023
Policy was reviewed: 1. Added TNF Inhibitors examples to try/fail criteria. 2. Removed Exception criteria from trial and failure for Rheumatoid Arthritis, Ulcerative Colitis and Crohn's Disease. 3. References were reviewed and updated.	01/01/2024	01/01/2024
Policy Reviewed: Removed the following: 1. Inadequate response or intolerance to one or more of the following: (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), Rinvoq, Simponi, Stelara, Xeljanz/XR. 2. "at up to maximally indicated doses"	03/15/2024	01/01/2024
Policy Reviewed: 1. Added new indication Polyarticular Juvenile Idiopathic Arthritis. 2. Updated reauthorization verbiage to "Member currently…excluding manufacturer samples." 3. Updated References.	05/10/2024	
Policy Reviewed: 1. Added Rinvoq LQ to drugs applied. 2. Removed prescribed requirement. 3. Removed BSA and SCORAD requirements. 4. References were reviewed and updated.	8/26/2024	09/12/2024