Clinical Policy Title:	upadacitinib
Policy Number:	RxA.745
Drug(s) Applied:	Rinvoq®
Original Policy Date:	04/18/2022
Last Review Date:	03/15/2024
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. Prescribed by or in consultation with a rheumatologist;
3. Trial and failure of a ≥ 3 months of at least one conventional systemic therapy (methotrexate [MTX], 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, Simponi/Simponi Aria;

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Inadequate response or intolerance to one preferred TNF inhibitor: adalimumab (adalimumab-adaz, Amjevita™, Hadlima, Humira, Yusimry), Cimzia, Enbrel, 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. Prescribed by or in consultation with a dermatologist;
3. 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;
4. Member meets (a and b);
   a. Trial and failure of any one of the following: medium to high potency topical corticosteroid, pimecrolimus cream, tacrolimus topical ointment, or Eucrisa (crisaborole) ointment, 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), unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Ulcerative colitis (must meet all):

1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
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, amino salicylate), 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), 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. Prescribed by or in consultation with a rheumatologist;
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, 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. Prescribed by or in consultation with a gastroenterologist;
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), Cimzia;

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

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication, excluding manufacturer samples;

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

References

1. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726. Available at: https://pubmed.ncbi.nlm.nih.gov/30499246/. Accessed January 01, 2024.
2. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis 2015; 0:1-12. doi:10.1136/annrheumdis-2015-208337. Available at: https://pubmed.ncbi.nlm.nih.gov/26644232/. Accessed January 01, 2024.
3. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008; 58:826-850. Available at: https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext. Accessed January 01, 2024.
4. Menter A, Gottlieb A, Feldman, SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol May 2008; 58(5): 826-50. Available at: https://pubmed.ncbi.nlm.nih.gov/18423260/. Accessed January 01, 2024.
5. Menter A, Korman NF, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 10.1016/j.jaad.2009.03.027. Available at: https://pubmed.ncbi.nlm.nih.gov/19493586/. Accessed January 01, 2024.
6. Menter A, Korman, NJ, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009; 60:643-659. Available at: https://pubmed.ncbi.nlm.nih.gov/19217694/. Accessed January 01, 2024.
7. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria. Arthritis and Rheumatism September 2010;62(9):2569-2581. Available at: https://pubmed.ncbi.nlm.nih.gov/20872595/. Accessed January 01, 2024.
8. Timmer A, McDonald JWD, Tsoulis DJ, Macdonald JK. Azathioprine and 6-mercaptopurine for maintenance of remission in ulcerative colitis. Cochrane Database Syst Rev. 2012;(9):CD000478. Available at: https://pubmed.ncbi.nlm.nih.gov/22972046/. Accessed January 01, 2024.
9. G-IBD Scores calculators in gastroenterology. Mayo Clinical Score. Available at: https://www.igibdscores.it/en/info-mayo-partial.html. Accessed January 01, 2024.
10. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127. Available at: https://pubmed.ncbi.nlm.nih.gov/16225367/. Accessed January 01, 2024.
11. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65:316-320. Available at: https://pubmed.ncbi.nlm.nih.gov/16096329/. Accessed January 01, 2024.
12. Braun J, van den Berg R, Baraliako X, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70:896-904. Available at: https://pubmed.ncbi.nlm.nih.gov/21540199/. Accessed January 01, 2024.
13. Ward M, Deodhar A, Akl E, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Available at: http://www.rheumatology.org. Accessed January 01, 2024.
14. Zochling J, van der Heijde D, Burgos-Vargas, R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006; 65:442-452. Available at: https://pubmed.ncbi.nlm.nih.gov/16126791/. Accessed January 01, 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	04/28/2022	07/18/2022

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. 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	11/18/2022	01/17/2023

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.		
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.	01/01/2024	01/01/2024

2. Removed Exception criteria from trial and failure for Rheumatoid Arthritis, Ulcerative Colitis and Crohn's Disease. 3. References were reviewed and updated.		
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