Clinical Policy Title:	adalimumab, adalimumab-atto, adalimumab-bwwd, adalimumab-aqvh, adalimumab-adaz
Policy Number:	RxA.726
Drug(s) Applied:	Humira®, Amjevita™, Hadlima™, Yusimry™, adalimumab-adaz
Original Policy Date:	04/18/2022
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 (e.g.,methotrexate [MTX], sulfasalazine, leflunomide, hydroxychloroquine), unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Juvenile Idiopathic Arthritis (must meet all)**:**

1. Diagnosis of PJIA;
2. Prescribed by or in consultation with a rheumatologist;
3. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (e.g., leflunomide or methotrexate) unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Ankylosing Spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS);
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;

Approval Duration

All Lines of Business (except Medicare): 12 months

E. Plaque Psoriasis (must meet all):
1. Diagnosis of Plaque Psoriasis (PsO);
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX], cyclosporin, acitretin) or phototherapy (psoralen plus ultraviolet A light [PUVA]) unless contraindicated or clinically significant adverse effects are experienced;

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

F. Crohn's Disease (must meet all):
1. Diagnosis of Crohn's Disease (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;

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

G. Ulcerative Colitis (must meet all):
1. Diagnosis of Ulcerative Colitis (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 (e.g., 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;

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

H. Hidradenitis Suppurativa (must meet all):
1. Diagnosis of moderate to severe Hidradenitis Suppurativa (HS);
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Documentation of Hurley stage II or stage III (see Appendix B);
4. Trial and failure of at least ≥ 3 months of systemic antibiotic therapy (e.g., clindamycin with rifampin, minocycline, doxycycline), unless contraindicated or clinically significant adverse effects are experienced;

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

I. Uveitis (must meet all):
1. Diagnosis of non-infectious intermediate, posterior, or panuveitis;

2. Prescribed by or in consultation with an ophthalmologist or a rheumatologist;
3. Member meets both (a and b):
   a. Trial and failure of at least ≥ 2-week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of at least one (1) conventional systemic therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil), unless contraindicated or clinically significant adverse effects are experienced;

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. 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 August 31, 2023.
2. 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 August 31, 2023.
3. 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 August 31, 2023.
4. 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 August 31, 2023.
5. Colombel JF, Sandborn WJ, Rutgeerts P, et.al. Adalimumab for Maintenance of Clinical Response and Remission in Patients with Crohn`s Disease: The CHARM Trial. Gastroenterology 2007; 132:52-65. Available at: https://pubmed.ncbi.nlm.nih.gov/17241859/. Accessed August 31, 2023.
6. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517. Available at: https://pubmed.ncbi.nlm.nih.gov/29610508/. Accessed August 31, 2023.
7. 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 August 31, 2023.
8. 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 August 31, 2023.
9. 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 August 31, 2023.
10. 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 August 31, 2023.
11. 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: https://www.rheumatology.org. Accessed August 31, 2023.
12. 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 August 31, 2023.
13. 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 August 31, 2023.
14. 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 August 31, 2023.
15. Alikhan A, Sayed C, Alavi A, et al. North American Clinical Management Guidelines for Hidradenitis Suppurativa: a publication from the United States and Canadian Hidradenitis Suppurativa Foundations. Part II: topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019; pii: S0190-9622(19)30368-8. doi: 10.1016/j.jaad.2019.02.068. Available at: https://pubmed.ncbi.nlm.nih.gov/30872149/. Accessed August 31, 2023.
16. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome Annals of the Rheumatic Diseases 2018;77:808-818. Available at: https://ard.bmj.com/content/annrheumdis/early/2018/04/06/annrheumdis-2018-213225.full.pdf. Accessed August 31, 2023.
17. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014; 147: 702-705. Available at: https://pubmed.ncbi.nlm.nih.gov/25046160/. Accessed August 31, 2023.
18. Bernell O, Lapidus A, Hellers G. Risk Factors for Surgery and Postoperative Recurrence in Crohn's Disease. Annals of Surgery. 2000; 231(1): 38-45. Available at: https://pubmed.ncbi.nlm.nih.gov/10636100/. Accessed August 31, 2023.
19. 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. Available at: https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext. Accessed August 31, 2023.

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.	01/05/2022	4/18/2022
Drug specific policy for Humira® was created based on	02/11/2022	4/18/2022

RxA.592.Biologics_DMARDs: 1. Initial Approval Criteria, I.A.5, I.H.6: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 40 mg/week. *Enter quantity limit for the dose of the indication consistent with FDA approved labeling. 2. Initial Approval Criteria, I.B.4: Updated to include new trial and failure criteria Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (leflunomide [Arava®] or methotrexate)unless contraindicated or clinically significant adverse effects are experienced; 3. Initial Approval Criteria, I.B.5, I.C.4, I.D.5, I.E.5, I.G.5, I.I.5: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 40 mg every other week. *Enter quantity limit for the dose of the indication consistent with FDA approved labeling. 4. Initial Approval Criteria, I.E.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 5. Initial Approval Criteria, I.F.5: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed (a or b): 6. Age ≥ 18 years: 40 mg every other week; 7. Age ≥ 6 years to 17 years: 80 mg every other week. *Enter quantity limit for the dose of the indication consistent with FDA approved labeling.		

8. Initial Approval Criteria, I.G.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 9. Continued Therapy Approval Criteria II.A.3 was updated to include *Enter quantity limit for the dose of the indication consistent with FDA approved labelling. 10. Appendix A: Updated to include abbreviations PUVA. 11. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 12. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 13. Appendix D, General Information: Updated to remove information regarding: (a, b, c, d, e, f, g and h) a. Rheumatoid Arthritis; b. Ulcerative Colitis; c. Medical justification supporting inability to use an immunomodulator for Crohn's disease; d. Definition of failure of MTX or DMARDs; e. Examples of positive response to therapy. f. Psoriatic Arthritis; g. The American Academy of Neurology (2018) Guidelines h. For female patients who are actively attempting to conceive. 14. References were reviewed and updated.		
Policy was reviewed: 1. Clinical Policy Title: Updated from "adalimumab" to	03/23/2023	04/13/2023

"adalimumab, adalimumab-atto" 2. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Amjevita™. 3. Background: Updated to include information regarding new drug Amjevita™. 4. Dosing Information, Drug Name: Updated to include new drug adalimumab-atto (Amjevita™). 5. Dosage Forms: Updated to include new brand dosage form, Single-dose prefilled SureClick® autoinjector: 40 mg/0.8 mL, Single-dose prefilled glass syringe: 20 mg/0.4 mL, 40 mg/0.8 mL. 6. Initial Approval Criteria, I.B.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed one of the following (a, b or c): a. Only for Humira®: Weight 10 kg (22 lbs) to <15 kg (33 lbs): 10 mg every other week; b. Weight 15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week; c. Weight ≥ 30 kg (66 lbs): 40 mg every other week. 7. Initial Approval Criteria, I.E.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed one of the following (a or b): a. Adults: 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29; b. Pediatrics (i or ii): i. Weight 17 kg (37 lbs.) to < 40 kg (88 lbs.): 80 mg on Day 1 and 40 mg on Day 15, followed by		

maintenance dose of 20 mg every other week starting Day 29; ii. Weight ≥ 40 kg (88 lbs): 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29. 8. Initial Approval Criteria. I.F.3: Updated to include new age criteria For Amjevita™: Age ≥ 18 years. 9. Initial Approval Criteria, I.F.4: Updated to include new diagnostic criteria Documentation of a Mayo Score ≥ 6. 10. Initial Approval Criteria, I.F.6: Updated dosing criteria from Dose does not exceed (a or b): a. Age ≥ 18 years: 40 mg every other week; b. Age ≥ 6 years to 17 years: 80 mg every other week to Dose does not exceed one of the following (a, b or c): a. For adults: 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every other week starting Day 29; b. For pediatric patients weighing more than 20 kg, but less than 40 kg: 80 mg on Day 1, 40 mg on Day 8 and Day 15, followed by maintenance doses of 40 mg every other week or 20 mg every week; c. For pediatric patients weighing more than 40 kg: 160 mg on Day 1 and 80 mg on Day 8 and 15, followed by maintenance doses of 80 mg every other week or 40		

mg every week. 11. Initial Approval Criteria, I.G.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose. 12. Initial Approval Criteria. I.H.2 and I.I.2: Updated to include new request criteria Request is for Humira. 13. Initial Approval Criteria, I.H.6: Updated dosing criteria from Dose does not exceed 40 mg/week to Dose does not exceed 160 mg on Day 1 and 80 mg on Day 15, followed by maintenance dose of 40 mg every week starting Day 29. 14. Initial Approval Criteria, I.I.5: Updated dosing criteria from Dose does not exceed 40 mg every other week to Dose does not exceed 80 mg initial dose, followed by maintenance dose of 40 mg every other week starting one week after initial dose. 15. For Amjevita™: All approval criteria updated to add that member must use 40 mg/0.8 mL prefilled SureClick® autoinjector with preferred formulary NDC (72511-0400-01 or 72511-0400-02). 16. Appendix B, Dosing Regimen, cyclophosphamide: Updated dosing information from 1 – 3 mg/kg/day orally to 1 – 3 mg/kg/day orally in combination with corticosteroids for indication Uveitis (off-label). 17. Appendix B, Dosing Regimen, mercaptopurine (Purixan®) : Updated dosing information		

from 50 mg orally once daily or 1– 2 mg/kg/day orally to 50 mg orally once daily or 1 – 1.5 mg/kg/day orally for indication Crohns disease Ulcerative colitis (off label) and Ulcerative colitis (off label). 18. Appendix B, Maximum Dose, mercaptopurine (Purixan®) : Updated maximum dose information from 2 mg/kg/day to 2.5 mg/kg/day for indication Crohns disease Ulcerative colitis (off label) and Ulcerative colitis (off label). 19. Appendix B, Dosing Regimen, Ilumya®: Updated dosing information from 100 mg subcutaneously at weeks 0 and 4 to 100 mg subcutaneously at weeks 0 and 4 and then every 12 weeks thereafter for indication Psoriasis. 20. Appendix D, General Information: Updated to include new information regarding mayo score which evaluates ulcerative colitis stage. 21. References were reviewed and updated.		
Policy was reviewed: 1. Dosage Forms, Amjevita™: Updated to include new dosage form, Single-dose prefilled syringe: 10 mg/0.2 mL" 2. Initial Approval Criteria, I.F.3.a: Updated to include new age criteria for Amjevita, Age ≥ 18 years. 3. Initial Approval Criteria, I.H.1: Updated indication from "Hiradenitis Suppurativa (HS)" to "Diagnosis of moderate to severe Hiradenitis Suppurativa (HS)" 4. Initial Approval Criteria, I.H.2: Updated to remove prior	06/05/2023	07/13/2023

approval criteria “Request is for Humira®”. 5. Initial Approval Criteria, I.H.3:Updated to add age requirement of ≥ 18 years for Amjevita™. 6. References were reviewed and updated.		
Policy was reviewed: 1. Updated Lines of Business Policy Applies to All lines of business (except Medicare) 2. Clinical Policy Title, Background, Dosing Information, Dosage forms and Clinical Policy: Updated to include information regarding new drug adalimumab-bwwd (Hadlima™), adalimumab-aqvh (Yusimry™) and adalimumab-adaz. 3. Background: Updated to include new indication Uveitis for Amjevita™. 4. Dosing Information, Indication: Updated to include new indication Uveitis for Amjevita™. 5. Dosage form updated. 6. Statement about provider sample was updated. 7. Initial Approval Criteria, I.A, I.C, I.D and I.G: Updated to remove prior age criteria "Age ≥ 18 years." 8. Initial Approval Criteria, I.H and I.I: Updated age criteria. Initial and Continued Therapy Approval criteria was updated to remove dosing criteria. 9. Initial Approval Criteria for Ulcerative Colitis updated to remove requirement for documentation of Mayo score. 10. Continued Therapy Approval Criteria, II.A.1: updated to “Member is currently receiving…”	08/31/2023	10/19/2023

11. Approval duration was updated to All Lines of Business (except Medicare): 12 months. 12. Appendix B: Therapeutic alternatives was removed. 13. Appendix C: Contraindications/Boxed Warnings was removed. 14. Renamed Appendix. 15. References were reviewed and updated.		
Policy was reviewed.	11/21/2023	11/21/2023