

Clinical Policy Title:	Adalimumab-afzb, adalimumab-bwwd, adalimumab-aaty
Policy Number:	RxA.726
Drug(s) Applied:	Abrilada, Hadlima, adalimumab-aaty, Yuflyma
Original Policy Date:	04/18/2022
Last Review Date:	12/11/2025
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 (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):

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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 that has been authorized by RxAdvance or the member has met initial approval criteria.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

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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.
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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.
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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.
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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 RxA.592.Biologics_DMARDs: 1. Initial Approval Criteria, I.A.5,	02/11/2022	4/18/2022

<p>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.</p> <p>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;</p> <p>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.</p> <p>4. Initial Approval Criteria, I.E.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D).</p> <p>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):</p> <p>6. Age ≥ 18 years: 40 mg every other week;</p> <p>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.</p> <p>8. Initial Approval Criteria, I.G.4: Updated trial and failure criteria</p>		
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<p>to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]).</p> <p>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.</p> <p>10. Appendix A: Updated to include abbreviations PUVA.</p> <p>11. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®.</p> <p>12. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs.</p> <p>13. Appendix D, General Information: Updated to remove information regarding: (a, b, c, d, e, f, g and h)</p> <ul style="list-style-type: none"> 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. <p>14. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. Clinical Policy Title: Updated from "adalimumab" to "adalimumab, adalimumab-atto"</p>	<p>03/23/2023</p>	<p>04/13/2023</p>

<ol style="list-style-type: none"> 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): <ol style="list-style-type: none"> 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): <ol style="list-style-type: none"> 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): <ol style="list-style-type: none"> 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 		
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<p>week starting Day 29;</p> <p>ii. Weight \geq 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.</p> <p>8. Initial Approval Criteria, I.F.3: Updated to include new age criteria For Amjevita™: Age \geq 18 years.</p> <p>9. Initial Approval Criteria, I.F.4: Updated to include new diagnostic criteria Documentation of a Mayo Score \geq 6.</p> <p>10. Initial Approval Criteria, I.F.6: Updated dosing criteria from Dose does not exceed (a or b):</p> <p>a. Age \geq 18 years: 40 mg every other week;</p> <p>b. Age \geq 6 years to 17 years: 80 mg every other week to Dose does not exceed one of the following (a, b or c):</p> <p>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;</p> <p>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;</p> <p>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.</p> <p>11. Initial Approval Criteria, I.G.5:</p>		
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<p>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.</p> <p>12. Initial Approval Criteria, I.H.2 and I.I.2: Updated to include new request criteria Request is for Humira.</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>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).</p> <p>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</p>		
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<p>orally once daily or 1 – 1.5 mg/kg/day orally for indication Crohns disease Ulcerative colitis (off label) and Ulcerative colitis (off label).</p> <p>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).</p> <p>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.</p> <p>20. Appendix D, General Information: Updated to include new information regarding mayo score which evaluates ulcerative colitis stage.</p> <p>21. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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 approval criteria “Request is for Humira®”. 	<p>06/05/2023</p>	<p>07/13/2023</p>

<p>5. Initial Approval Criteria, I.H.3: Updated to add age requirement of ≥ 18 years for Amjevita™.</p> <p>6. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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-bwvd (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..." 11. Approval duration was updated to All Lines of Business (except Medicare): 12 months. 	<p>08/31/2023</p>	<p>10/19/2023</p>

<ul style="list-style-type: none"> 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
Updated drug list	9/12/2024	9/12/2024
Policy was reviewed.	12/05/2024	N/A
Policy was reviewed: <ul style="list-style-type: none"> 1. Yuflyma added to policy 	12/11/2025	12/11/2025