

Clinical Policy Title:	abatacept
Policy Number:	RxA.741
Drug(s) Applied:	Orencia®
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;
2. 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;
*Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;
3. Trial and failure of at least two (2) of the following agents: adalimumab (Abrilada™, Hadlima™, or adalimumab-aaty), Cimzia, Enbrel, Rinvoq, Simponi/ Simponi Aria, or Xeljanz/ XR unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of Psoriatic Arthritis;
2. Trial and failure of at least two (2) of the following agents: adalimumab (Abrilada™, Hadlima™, or adalimumab-aaty), Cimzia, Enbrel, Rinvoq, Rinvoq LQ, Simponi/Simponi Aria, Stelara, Skyrizi, Tremfya or Xeljanz/ XR unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (must meet all):

1. Diagnosis of PJIA;
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;
*Exception: If one biologic DMARD that is FDA-approved for rheumatoid arthritis has been previously tried, then trial of a conventional systemic agent is not required;
3. Trial and failure of any two (2) of the following agents: adalimumab (Abrilada™, Hadlima™, or adalimumab-aaty), Enbrel, Rinvoq, Rinvoq LQ, or Xeljanz, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

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.

All Lines of Business (except Medicare): 12 months

D. Prophylaxis for Acute Graft vs Host Disease (must meet all):

1. Prescribed for prophylaxis of acute graft vs host disease undergoing hematopoietic stem cell transplantation from a matched or 1 allele mismatched unrelated- donor;
2. Used in combination with a calcineurin inhibitor and methotrexate.

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. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Entesitis (nih.gov). Accessed August 26, 2024.
4. Orencia. Package insert. Bristol-Myers Squibb. 2017. 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.Biologic_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Tysabri was created based on RxA.592.Biologic_DMARDs <ol style="list-style-type: none"> 1. Dosing Information for (Orencia®) was updated to include indication and dosing information for Acute Graft Vs Host Disease prophylaxis (aGVHD). 2. Initial Approval Criteria, I.A.5: Updated to remove prior trial and failure criteria "Failure of two (2) of the following, each used for ≥ 3 	02/14/2022	04/18/2022

<p>months, unless contraindicated or clinically significant adverse effects are experienced: Humira®, Cimzia®, Inflectra®, Rinvoq™, Renflexis™, Simponi®, Simponi Aria®, or Xeljanz®/ Xeljanz XR®".</p> <p>3. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria Trial and failure of at least two (2) of the following agents: Cimzia®, Humira®, Simponi®/ Simponi Aria®, Rinvoq® or Xeljanz/XR® unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.</p> <p>4. Initial Approval Criteria, I.B.5: Updated to remove prior trial and failure criteria Failure of a trial of two (2) of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Humira®, Inflectra®, Otezla®, Renflexis™, Rinvoq™, Simponi®, Simponi Aria®, Stelara®, Taltz®, or Xeljanz®/ Xeljanz XR®;</p> <p>5. Initial Approval Criteria, I.C.5: Updated to include new trial and failure criteria Trial and failure of Humira® unless contraindicated or clinically significant adverse effects experienced; *Exception: If a total of two TNF inhibitors (Humira, Simponi Aria, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.</p> <p>6. Initial Approval Criteria, I.D: Updated to include approval criteria for indication Prophylaxis</p>		
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<p>for Acute Graft Vs host disease (aGVHD).</p> <ol style="list-style-type: none"> 7. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 8. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 9. Appendix D, General Information: Updated to remove information regarding: Rheumatoid Arthritis. 10. References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5: Updated trial and failure criteria to include drug Enbrel®. 2. Initial Approval Criteria, I.A.5 and I.C.5: Updated to remove exception about trial and failure criteria "*Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required." 3. Initial Approval Criteria, I.B.4: Updated trial and failure criteria from Trial and failure of at least two (2) first line agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, Stelara®, Stelara®, Skyrizi®, Tremfya® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®/ Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required to Trial and failure of at least two (2) of the following agents: Humira®, 	<p>10/03/2022</p>	<p>10/19/2022</p>

<p>Cimzia®, Enbrel®, Rinvoq®, Simponi®/ Simponi Aria®, Stelara®, Skyrizi®, Tremfya® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced.</p> <p>4. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.C.5: Updated to add Xeljanz® in the trial and fail criteria. 2. Initial Approval Criteria I.C.5: Updated to add *Trial of Xeljanz® requires inadequate response to one or more TNF inhibitors. 3. Initial Approval Criteria I.A.5 and I.B.4: Updated to add *Trial of Xeljanz/XR®, Rinvoq® requires inadequate response to one or more TNF inhibitors. 4. References were reviewed and updated. 	01/03/2023	01/17/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5, I.B.4 and I.C.5: Updated trial and failure criteria to include new preferred brand, Amjevita™. 2. References were reviewed and updated. 	04/03/2023	04/13/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Updated trial and failure criteria to include Humira biosimilar. 2. Removed age criteria. 3. Removed dose criteria. 4. Updated Approval duration. 5. Removed reauthorization requirement for positive response to therapy. 6. References were reviewed and updated. 	11/10/2023	02/28/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber requirement. 	8/27/2024	09/12/2024

<ol style="list-style-type: none"> 2. Added Rinvoq and Rinvoq LQ as trial and failure option for PJIA and PsA. 3. References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Update Humira biosims to covered formulary alternatives: Abrilada, Hadlima, adalimumab-aaty 	<p>2/13/2025</p>	
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>