

EVH Clinical Guideline 5051.CC for Orencia (abatacept)

Guideline Number: EVH_CG_5051.CC	<u>Applicable Codes</u>	
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Original Date: March 2022	Last Revised Date: July 2026	Implementation Date: October 2026

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for Orencia® (abatacept)

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate® Lexidrug™, Elsevier Clinical Pharmacology).

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the General Criteria **and** diagnosis-specific sections below.

General Criteria

- Must have a negative tuberculosis skin test collected within the last 6 months
 - Example acceptable testing includes the Tuberculin PPD (purified protein derivative) test or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must have documentation of screening for viral hepatitis
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baricitinib), or Otezla (apremilast))
- Must have documentation or an attestation from the provider that the member is updated on all vaccinations in accordance with current vaccination guidelines
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on

diagnosis, weight, etc.) listed in the FDA approved labeling.

Chronic graft versus host disease (cGVHD) (*off-label supported indication*)

- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Must have had an inadequate response to systemic corticosteroids or have an intolerance/contraindication to this therapy

Immune checkpoint inhibitor-related toxicity (*off-label supported indication*)

- Must be prescribed by, or in consultation with, an oncologist or hematologist
- Must have myocarditis
- Must have documentation of ONE of the following:
 - A previous inadequate response to systemic corticosteroids or have an intolerance/contraindication to this therapy
 - Concomitant myositis and the requested drug will be used in combination with ruxolitinib

Juvenile Idiopathic Arthritis, includes Polyarticular Juvenile Arthritis (PJIA) & Oligoarticular Juvenile Arthritis

- Must be prescribed by, or in consultation with, a rheumatologist
- Must be age 2 years or older
- Must have a diagnosis of moderately to severely active juvenile idiopathic arthritis
- Must meet ALL criteria in at least ONE of the following sections:
 - Must have risk factors for disease severity and potentially a more refractory disease course (i.e., positive rheumatoid factor, positive anti-cyclic citrullinated peptide antibodies or pre-existing joint damage) **AND** have ONE of the following:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease
 - OR**
 - Must have had a trial and failure of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) **AND** has one of the following risk factors for poor outcomes:

- Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
- Presence of erosive disease or enthesitis
- Delay in diagnosis
- Elevated levels of inflammation markers
- Symmetric disease

OR

- Must have documentation showing an inadequate response to at least a 3-month trial of methotrexate, leflunomide, sulfasalazine, or hydroxychloroquine OR have an intolerance or contraindication to conventional DMARDs (see Appendix 1)
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
 - An adalimumab product
 - Cimzia
 - Enbrel
 - Rinvoq
 - Xeljanz

Psoriatic Arthritis

- Must be prescribed by, or in consultation with, a rheumatologist or dermatologist
- Must be age 2 years or older
- Must have a diagnosis of active psoriatic arthritis, with the severity and symptoms of disease documented
- For mild-to-moderate disease *only*, must have ONE of the following:
 - Must have had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) or have a contraindication or intolerance to all drugs (see **Appendix 1**)
 - Must have enthesitis or predominantly axial disease
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
 - An adalimumab product
 - Cimzia
 - Cosentyx
 - Enbrel

- Rinvok
- Xeljanz

Prophylaxis of Acute Graft versus Host Disease (aGVHD)

- Must be prescribed by, or in consultation with, a transplant specialist or an oncologist/hematologist
- Must be age 2 years or older
- Must be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1-allele-mismatched unrelated donor
- Must be used in combination with a calcineurin inhibitor and methotrexate, unless not tolerated or contraindicated

Rheumatoid Arthritis

- Must be prescribed by, or in consultation with, a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have documentation of testing of the following:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
– *not required if RF & anti-CCP are positive*
- Must submit documentation of baseline activity, such as tender joint count, swollen joint count, pain, or disability
- Must have documentation showing ONE of the following:
 - Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week)
 - Member has an intolerance or contraindication to methotrexate (see **Appendix 1**)
- Must have an adequate trial (of at least 3 months) and failure of at least two (2) of the following with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies:
 - An adalimumab product
 - Cimzia
 - Enbrel
 - Rinvok
 - Xeljanz

REAUTHORIZATION CRITERIA

Reauthorization requests for prophylaxis of acute Graft Versus Host Disease and immune checkpoint inhibitor related toxicity must meet initial criteria at each review.

For all other diagnoses (if applicable): all prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon meeting **general reauthorization criteria and diagnosis-specific criteria.**

General Reauthorization Criteria

- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD (such as Xeljanz (tofacitinib), Olumiant (baricitinib), or Otezla (apremilast))
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Chronic graft versus host disease (cGVHD) (*off-label supported indication*)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms

Rheumatoid Arthritis (RA)

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Juvenile Idiopathic Arthritis, includes Polyarticular Juvenile Idiopathic Arthritis (PJIA) & Oligoarticular Juvenile Arthritis

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:
 - Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
 - Number of joints with limitation of movement
 - Functional ability

Psoriatic Arthritis

- Must have recent chart note documentation showing achievement or maintenance of a positive clinical response as evidenced by low disease activity OR improvement in at least ONE of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

APPROVAL DURATIONS

Initial Authorization	Up to one year
Reauthorization	Same as initial

APPENDICES

Appendix 1 – Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

CODING AND STANDARDS

Codes

Code	Brand	Description
J0129	Orencia	Injection abatacept 10 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Orencia® (abatacept) is indicated for:

- Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adults with moderately to severely active rheumatoid arthritis (RA)
- Reducing signs and symptoms in pediatric patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA).
- Treatment of active psoriatic arthritis in patients 2 years of age and older
- Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

POLICY HISTORY

Date	Summary
July 2026	• Updated criteria for all indications under Initial Criteria, including specifying biologic therapy prerequisites (as applicable) • Added reauthorization criteria for chronic graft versus host disease • Added Rinvoq as a preferred agent

Date	Summary
October 2024	• Updated age limit for Psoriatic Arthritis • Select revisions to existing diagnoses to match pharmacy benefit criteria • Added 2 new indications – cGVHD and immune checkpoint inhibitor toxicity • Added 6-month limitation on TB testing
March 2022	• Initial Review

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; November 2025.
2. Genovese MC, Becker JC, Schiff M, Luggen M, Sherrer Y, Kremer J, Birbara C, Jane Box J, Natarajan K, Nuamah I, Li T, Aranda R, Hagerty DT, Dougados M. Abatacept for Rheumatoid Arthritis Refractory to Tumor Necrosis Inhibition. N Engl J Med 2005;353(21): 1114-23
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2021;73(7):1108-1123
4. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis infection – United States 2010. Department of Health and Human Services Centers for Disease Control and Prevention [U.S.]. vol 59, RR-5. 2010 June 25.
5. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care & Research* 2011;63(4):465-482
6. Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection. <http://www.cdc.gov/tb/publications/factsheets/testing/IGRA.htm>. Accessed 10/29/2012.
7. Ringold S, Weiss PF, Beukelman T, DeWitt EM, Ilowite NT, Kimura Y, Laxer RM, Lovell DJ, Nigrovic PA, Robinson AB and Vehe RK (2013), 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis Care Res*, 65: 1551–1563
8. Hamilton BK. Current approaches to prevent and treat GVHD after allogeneic stem cell transplantation. *Hematology Am Soc Hematol Educ Program*. 2018;2018(1):228-235.
9. 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 Rheumatol.* 2019;71(1):5-32
10. Smolen JS, Landewé RBM, Bijlsma JWW, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis.* 2023;82(1):3-18. doi:10.1136/ard-2022-223764.
11. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2021;73(7):924-939. doi:10.1002/acr.24596
12. Fautrel B, Mitrovic S, De Matteis A, et al. EULAR/PRoS recommendations for the diagnosis and management of Still's disease, comprising systemic juvenile idiopathic arthritis and adult-onset Still's disease. *Annals of the Rheumatic Diseases* Published Online First: 24 September 2024.