Abatacept (Orencia®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Moderately to severely active rheumatoid arthritis (RA) in adults
2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age or older
3. Active psoriatic arthritis (PsA) in patients 2 years of age and older
4. 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

B. Compendial Uses
1. Oligoarticular juvenile idiopathic arthritis
2. Chronic graft versus host disease
3. Immune checkpoint inhibitor-related toxicity

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Rheumatoid arthritis (RA)
1. Initial requests:
   i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Articular juvenile idiopathic arthritis (JIA)
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Psoriatic arthritis (PsA)
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Chronic graft versus host disease and immune checkpoint inhibitor-related toxicity: For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis and articular juvenile idiopathic arthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Prophylaxis of acute graft versus host disease (aGVHD), chronic GVHD, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. Member meets either of the following criteria:
      a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Articular juvenile idiopathic arthritis (JIA)

1. Authorization of 12 months may be granted for members 2 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic arthritis.

2. Authorization of 12 months may be granted for members 2 years of age and older for treatment of moderately to severely active articular juvenile idiopathic arthritis when any of the following criteria is met:
   i. Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
   ii. Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers
      e. Symmetric disease
   iii. Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and member also meets one of the following:
      a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
      b. Has high disease activity.
      c. Is judged to be at high risk for disabling joint disease.

C. Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

2. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis
   ii. Member has severe disease.

D. Prophylaxis of acute graft versus host disease

Authorization of 1 month may be granted for prophylaxis of acute graft versus host disease in members 2 years of age and older when both of the following criteria are met:

1. Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.
2. The requested medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

E. Chronic graft versus host disease

Authorization of 12 months may be granted for treatment of chronic graft versus host disease when either of the following criteria is met:

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

F. Immune checkpoint inhibitor-related toxicity
Authorization of 6 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has myocarditis and meets either of the following:
1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)
Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain 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.

B. Articular juvenile idiopathic arthritis (JIA)
Authorization of 12 months may be granted for all members 2 years of age and older (including new members) who are using the requested medication for moderately to severely active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

C. Psoriatic arthritis (PsA)
Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement
6. Functional status
7. C-reactive protein (CRP)

D. Prophylaxis of acute graft versus host disease, chronic graft versus host disease, and immune checkpoint inhibitor-related toxicity
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

VI. OTHER

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

VII. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VIII. APPENDICES

Appendix A: Examples of clinical reasons to avoid pharmacologic treatment with methotrexate or leflunomide

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

Appendix B: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Orencia (Abatacept)	Acute Graft Versus Host Disease, Prophylaxis	Route of Administration: Intravenous 2-5 Years 15mg/kg on the day before transplantation (day -1), then 12 mg/kg on day 5, 14, and 28 after transplant ≥6 Years 10mg/kg (up to max 1000 mg) on the day before transplantation (day -1), then on day 5, 14, and 28 after transplant
Orencia (Abatacept)	Chronic Graft Versus Host Disease	Route of Administration: Intravenous Initial: 10mg/kg on weeks 0, 2, and 4 Maintenance: 10mg/kg every 4 weeks
Orencia (Abatacept)	Immune Checkpoint Inhibitor-Related Toxicity	Route of Administration: Intravenous 500mg every 2 weeks for 5 doses

Orencia (Abatacept)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Subcutaneous ≥2 Years 10kg to <25kg 50mg every week 25kg to <50kg 87.5mg every week ≥50kg 125mg every week
Orencia (Abatacept)	Polyarticular Juvenile Idiopathic Arthritis or Oligoarticular Juvenile Idiopathic Arthritis	Route of Administration: Intravenous ≥6 Years <75kg Initial:10mg/kg on weeks 0, 2, and 4 Maintenance: 10mg/kg every 4 weeks 75-100kg Initial: 750mg on weeks 0, 2, and 4 Maintenance: 750mg every 4 weeks ≥ 101kg Initial: 1000mg on weeks 0, 2, and 4 Maintenance: 1000mg every 4 weeks
Orencia (Abatacept)	Psoriatic Arthritis	Route of Administration: Subcutaneous 2- <18 Years 10-24kg 50mg every week 25-49kg 87.5mg every week ≥50kg 125mg every week ≥18 Years 125mg every week
Orencia (Abatacept)	Psoriatic Arthritis	Route of Administration: Intravenous ≥18 Years <60kg Initial: 500mg on weeks 0, 2, and 4 Maintenance: 500mg every 4 weeks 60-100kg Initial: 750mg on weeks 0, 2, and 4 Maintenance:750mg every 4 weeks >100kg Initial: 1000mg on weeks 0, 2, and 4 Maintenance: 1000mg every 4 weeks

Orencia (Abatacept)	Rheumatoid Arthritis	Route of Administration: Subcutaneous ≥18 Years 125mg every week (Prior to first subcutaneous dose, may administer an optional loading dose may be administered as a single intravenous infusion as per body weight categories)
Orencia (Abatacept)	Rheumatoid Arthritis	Route of Administration: Intravenous ≥18 Years <60kg Initial: 500mg on weeks 0, 2, and 4, followed by Maintenance: 500mg every 4 weeks 60-100kg Initial: 750mg on weeks 0, 2, and 4, followed by Maintenance: 750mg every 4 weeks ≥100kg Initial: 1000mg on weeks 0, 2, and 4, followed by Maintenance: 1000mg every 4 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE 10/31/2024

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