Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/03/2024

Orencia® (abatacept)

HCPCS: J0129

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. Diagnosis of rheumatoid arthritis (RA)
      i. Trial and failure of at least a 3-month trial of one disease-modifying anti-rheumatic drug (DMARD) unless contraindicated or not tolerated. Examples include: methotrexate, hydroxychloroquine, leflunomide, sulfasalazine
   c. Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)
      i. Trial and failure of at least a 3-month trial of one DMARD unless contraindicated or not tolerated. Examples include: methotrexate and leflunomide
   d. Diagnosis of psoriatic arthritis (PsA)
   e. For prophylaxis of acute graft versus host disease (aGVHD)
      i. Used in combination with a calcineurin inhibitor and methotrexate
      ii. Undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor
   f. Not to be used in combination with other biologics or targeted DMARDs for the same indication
   g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents.

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Orencia is a biologic disease-modifying agent that functions as a selective T-cell costimulation blocker. It is approved to treat RA, JIA, PsA as monotherapy or concomitantly with DMARDs, and as prophylaxis for aGVHD, in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing HSCT from a matched or 1 allele-mismatched unrelated donor. Concomitant use with other potent immunosuppressants (including other biologics and targeted DMARDs like Janus kinase (JAK) inhibitors), however, is not recommended.

- Orencia may be administered as a subcutaneous injection or an intravenous (IV) infusion for RA, JIA, and PSA and administered IV for prophylaxis of aGVHD. Of note, subcutaneous Orencia is indicated for children 2 years of age and older with JIA, whereas administration of Orencia as an IV infusion should only be used in children 6 years of age and older with JIA. Refer to the prescribing information for additional details

- Rheumatoid Arthritis

    - The 2021 American College of Rheumatology (ACR) Guidelines for the Treatment of Rheumatoid Arthritis (RA) established recommendations for the care of adult RA patients. The guidelines state that treatment decisions should follow a shared decision-making process and should be reevaluated within a minimum of 3 months based on the efficacy and tolerability of the DMARD(s) chosen.

    - For the initial treatment of symptomatic RA, the guidelines strongly recommend the use of conventional synthetic DMARD (csDMARD) monotherapy in those who are DMARD-naive. csDMARD monotherapy is a less costly first line treatment option with an extensive safety record accompanied by well-documented clinical efficacy and a large body of clinical experience and familiarity among prescribers. csDMARDs in the guidelines refer to methotrexate (MTX), hydroxychloroquine, leflunomide (LEF), and sulfasalazine. Azathioprine, cyclosporine, minocycline, and gold were not included due to their infrequent use in RA and lack of new data since the prior guidelines were published. Oral MTX is recommended as the preferred initial DMARD for patients with moderate-to-high disease activity, and hydroxychloroquine is recommended as the preferred initial DMARD for patients with low disease activity.

    - If disease activity remains moderate or high despite optimal dosing of methotrexate monotherapy, the use of dual therapy with methotrexate plus biologic DMARD (bDMARD; etanercept, adalimumab, infliximab, golimumab, certolizumab pegol, abatacept, tocilizumab, sarilumab, rituximab) or targeted synthetic DMARD (tsDMARD; tofacitinib, baricitinib, upadacitinib) therapy is conditionally recommended over the use of triple therapy (i.e., addition of sulfasalazine and hydroxychloroquine). The guidelines do not inform preference of bDMARD over tsDMARD therapy, or vice-versa, for use in combination with MTX. No one agent has been shown to be superior to another. The guidelines do acknowledge the emergence of safety signals for the JAK inhibitor class (tsDMARD), and state that further modification of this recommendation may be necessary as additional data are published.

    - A treat-to-target approach is conditionally recommended over usual care for patients who have had an inadequate response to bDMARDs or tsDMARDs. Treat-to-target refers to a systematic approach involving frequent monitoring of disease activity using validated instruments and modification of treatment to minimize disease activity with the goal of reaching a pre-defined target (low disease activity or remission).

- Juvenile Idiopathic Arthritis

    - Juvenile idiopathic arthritis (JIA) defines a collection of inflammatory arthritides of unknown etiology. Onset is prior to 16 years of age with a minimum duration of 6 weeks and other potential causes of synovitis are excluded. JIA can be subdivided into polyarticular JIA and systemic JIA.

    - Polyarticular JIA (pJIA) is defined by the presence of more than 4 affected joints in the first 6 months of illness and comprises 20-30% of children with JIA. Therapy is directed toward treating the underlying inflammation and preventing JIA-associated complications and adverse effects of its treatment.

    - The 2019 American College of Rheumatology/Arthritis Foundation (ACR/AF) guideline for the treatment of JIA strongly recommends initial therapy for pJIA with a DMARD such as MTX or LEF. MTX is conditionally recommended over LEF as it has a greater volume of data supporting its effectiveness compared to leflunomide and can be administered subcutaneously (recommended) or orally. The guidelines consider an adequate trial of a DMARD to be 3 months.

    - If moderate or high disease activity persists despite an adequate DMARD trial, the ACR/AF guidelines recommend biologic agents either in combination with a DMARD or as monotherapy in certain situations. Biologic agents FDA approved for pJIA in patients 2 years of age and older include Humira® (adalimumab), Enbrel® (etanercept), Actemra® (tocilizumab), Orencia (abatacept), Simponi Aria® (golimumab), Xeljanz® (tofacitinib), and Xeljanz (tofacitinib) oral solution.

        - Of note, biologic therapy may be an appropriate initial therapy in pJIA patients with risk factors and involvement of high-risk joints, high disease activity, and/or for those judged to be at high risk of disabling joint damage.

    - There is the most experience with tumor necrosis factor inhibitors (TNFi; Humira, Enbrel, Simponi Aria) as initial biologic therapy; however, the preferred class of initial biologic is not specified in the guideline recommendations due to a lack of comparative data and the consideration that non-TNFi biologics may be preferred in certain patient-specific scenarios. If a TNFi is started as the initial biologic, switching to a non-TNFi (tocilizumab or abatacept) is recommended over switching to a second TNFi. An exception to this is for those who had a good initial response to the first TNFi.

- Psoriatic Arthritis

    - Psoriatic Arthritis (PsA) is a chronic inflammatory disease often associated with psoriasis. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches. These patches, called plaques, may appear anywhere on the body. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur.

    - Per the 2018 American College of Rheumatology (ACR)/National Psoriasis Foundation (NPF) guideline for the treatment of psoriatic arthritis: All recommendations for treatment-naive patients with active PsA are conditional based on low- to very-low quality evidence.

    - In treatment-naïve patients, oral systemic medications (OSMs), such as methotrexate, sulfasalazine, cyclosporine, and leflunomide, may be used in patients without severe psoriatic arthritis and without severe psoriasis. OSMs have robust longitudinal safety and efficacy data in patients with PsA. Maximal response to OSMs is most commonly achieved within 3 months of therapy.

- If PsA remains active despite OSM therapy, switching to a TNFi, an interleukin-17 inhibitor (IL-17i), or an IL-12/23i biologic is recommended over switching to a different OSM; switching to a TNFi biologic over an IL-17i or IL-12/23i biologic is conditionally recommended in this scenario based on moderate quality evidence. Additional treatment options include Orencia (abatacept) and Xeljanz (tofacitinib). The detailed recommendations for subsequent therapies can be found in the 2018 ACR/NPF guideline for the treatment of psoriatic arthritis.

– Prophylaxis for Acute Graft vs. Host Disease

- Prophylaxis of aGVHD centers on immunosuppression of the donor cells, either pharmacologically or via T cell depletion. There is no agreed-upon standard regimen, and clinical practice varies by institution. Guidelines for GVHD prophylaxis have been proposed by the European Group for Blood and Marrow Transplantation (EBMT) and European LeukemiaNet (2020).

- According to the EBMT, the consensus recommendations for the prophylaxis of GVHD in allogenic transplantation with myeloablative conditions has the standard prophylaxis being cyclosporine plus a short course of methotrexate. Tacrolimus plus methotrexate is regarded as equivalent, but experience in Europe is too limited to support recommendations. Antithymocyte globulin has been shown to reduce chronic GVHD and improve the quality of life in transplantations from an unrelated donor. Therefore, antithymocyte globulin can be included in the prophylaxis regimen for unrelated donor transplantations. GVHD prophylaxis for reduced intensity conditioning has the standard prophylaxis being cyclosporine plus mycophenolate mofetil. Orencia has not been included in the EBMT proposed guidelines.

- Donor selection for HSCT is a critical element contributing to the success of the transplant. Matching donor and recipient for human leukocyte antigen (HLA) class I (-A, -B, and -C) and class II (-DRB1 and -DQB1) haplotypes is a key part of successful allogeneic HSCT. Molecular typing, used for allele matching, defines HLA genes by their DNA sequences. Molecular typing is necessary for HLA matching in unrelated donor transplants. An 8 of 8 HLA match refers to donor-recipient pairs matched for HLA-A, HLA-B, HLA-C, and HLA-DRB1 at the allele level. A 7 of 8 HLA match refers to pairs with a single allele or antigen mismatch at either HLA-A, HLA-B, HLA-C, or HLA-DRB1. In the Study GVHD-1, participants were either in an 8 of 8 HLA-matched cohort or a 7 of 8 HLA-matched cohort.

References:

1. Ringold et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of JIA. Arthritis Care and Research. Vol 71 No 6 Jun 2019.
2. Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021 Jul; 73 (7):924-939.
3. Singh JA, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016 Jan; 68(1): 1-26.
4. Penack O, Marchetti M, Ruutu T, et al. Prophylaxis and management of graft versus host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. Lancet Haematol. 2020 Feb;7(2):e157-e167. doi: 10.1016/S2352-3026(19)30256-X. PMID: 32004485.
5. Orencia (abatacept) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; November 2023.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.7</td><td>Effective Date: 10/03/2024</td><td>Added “for the same indication” to the not to be used in combination with other biologics or targeted DMARDs criteria</td></tr>
<tr><td>2.6</td><td>Effective Date: 02/08/2024</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.5</td><td>Effective Date: 02/02/2023</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.4</td><td>Effective Date: 02/10/2022</td><td>Updated to include Orencia’s new indication for prophylaxis of acute graft versus host disease</td></tr>
<tr><td>2.3</td><td>Effective Date: 12/09/2021</td><td>Removed FDA approved indication and the oral DMARD criteria for psoriatic arthritis.</td></tr>
<tr><td>2.2</td><td>Effective Date: 12/03/2020</td><td>Criteria updated to align management between pharmacy and medical benefit for all listed indications.</td></tr>
<tr><td>2.1</td><td>Effective Date: 10/08/2020</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.0</td><td>Effective Date: 11/07/2019</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.9</td><td>Effective Date: 11/01/2018</td><td>Added trial of all preferred drugs to apply to all indications</td></tr>
<tr><td>1.8</td><td>Effective Date: 10/01/2018</td><td>UM medical management system update for BCNA
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<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>Yes</td></tr>
<tr><td>BCNA</td><td>Yes</td></tr>
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<tr><td>1.7</td><td>Effective Date: 08/09/2018</td><td>Updated language to include preferred infliximab product</td></tr>
<tr><td>1.6</td><td>Effective Date: 11/09/2017</td><td>SQ approval for 2 years of age for JIA and New FDA approval for PsA</td></tr>
<tr><td>1.5</td><td>Effective Date: 07/05/2017</td><td>UM medical management system update for MAPPO
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<tr><td>1.4</td><td>Effective Date: 03/23/2017</td><td>New coverage criteria for biologics that treat rheumatoid conditions</td></tr>
<tr><td>1.3</td><td>Effective Date: 11/10/2016</td><td>New criteria document: Expanded criteria for JIA</td></tr>
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07/01/2016</td><td>UM medical management system update for BCN
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
ORENCIA® (abatacept) J0129

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

This form is to be used by participating physicians to obtain coverage for ORENCIA®. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female **Pt weight (in kg)** **Date recorded:**_____	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. How is this medication being administered? ☐ Self-administered ***(Please fax this completed form to BCBSM at (866) 601-4425)***
   ☐ Healthcare professional administered ***(Continue to #3)***
3. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
4. Please specify location of administration if hospital outpatient infusion: _____
5. Please provide the NPI number for the place of administration: _____

6. **Initiation AND Continuation of therapy:**
   a. Will the patient be receiving Orencia with other biologic agents (for example: Remicade, Humira, Stelara, Cosentyx, Entyvio, or Tremfya, etc.) or targeted DMARD medications (for example: Otezla)?
      ☐ Yes, Comment: _____ ☐ No
   b. Please check patient's diagnosis:
      ☐ Rheumatoid arthritis
      ☐ Juvenile idiopathic arthritis
      ☐ Psoriatic arthritis
      ☐ Prophylaxis of acute graft versus host disease (**aGVHD**; go to d)
      ☐ Other, list diagnosis: _____
   c. Has the patient tried and failed therapy with at least one conventional therapy?
      ☐ Methotrexate, Date started: _____ Date ended: _____
      ☐ Sulfasalazine, Date started: _____ Date ended: _____
      ☐ Hydroxychloroquine, Date started: _____ Date ended: _____
      ☐ Leflunomide, Date started: _____ Date ended: _____
      ☐ Other: _____, Date started: _____ Date ended: _____
   d. **aGVHD:** Which medications will the patient be receiving Orencia with?
      ☐ Methotrexate ☐ Cyclosporine ☐ Tacrolimus ☐Other: _____
   e. **aGVHD:** Will the patient be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor?
      ☐ Yes, Comment: _____ ☐ No

7. **Continuation Request: Orencia start date: _____**
   a. Have the patient's signs and symptoms improved with Orencia?
      ☐ Yes ☐ No, Comment: _____

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	**Physician Signature**	**Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ Prior Treatments with traditional DMARD
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

01/21/14; 10/19/2015; 11/9/2016; 12/28/2016; 8/11/2017;12/5/2017; 2/2/2018; 7/24/2018, 9/18/2018; 3/7/2019; 12/3/2021; 2/10/2022