

## PHARMACY POLICY STATEMENT

### Marketplace

<b>DRUG NAME</b>	<b>Orencia (abatacept)</b>
BILLING CODE	J0129 for infusion Must use valid NDC for self-administered product
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient/Inpatient
STATUS	Prior Authorization Required

Orencia is an immunomodulator that inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86 to block interaction with CD28. This interaction would provide a costimulatory signal needed for full activation of T cells. Activated T cells are implicated in the pathogenesis of RA, pJIA, and PsA. In GVHD, donor T cells would be induced to attack the host if the signaling process was not blocked.

Orencia (abatacept) will be considered for coverage when the following criteria are met:

#### Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has had an adequate trial and failure of a non-biologic DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated; AND
4. Member must have tried and failed treatment with **two** preferred biologic DMARDs (see Appendix). Treatment failure requires at least 12 weeks of therapy with each drug.
5. Member has had a negative tuberculosis (TB) test within the past 12 months.
6. **Dosage allowed/Quantity limit:**
  - a) Intravenous (6 years and older only): one weight-based IV infusion on week 0, 2, 4, and every 4 weeks thereafter.
    - i) Less than 75 kg: 10 mg/kg;
    - ii) 75 kg to 100 kg: 750 mg (3 vials);
    - iii) More than 100 kg: 1000 mg (4 vials).
  - b) Subcutaneous:
    - i) 10 kg to < 25 kg: 50 mg once weekly;
    - ii) 25 kg to < 50 kg: 87.5 mg once weekly;
    - iii) 50 kg or more: 125 mg once weekly.

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Psoriatic Arthritis (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
  - a) Non-biologic DMARD is not required for:
    - i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
  - b) NSAID and non-biologic DMARD are not required for:
    - i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be a TNF inhibitor (same class as Humira, see Appendix); AND
6. Member has had a negative tuberculosis (TB) test within the past 12 months.
7. **Dosage allowed/Quantity limit:**
  - a) Intravenous: one weight-based IV infusion on week 0, 2, 4, and every 4 weeks thereafter.
    - i) Less than 60 kg: 500 mg (2 vials);
    - ii) 60 to 100 kg: 750 mg (3 vials);
    - iii) More than 100 kg: 1000 mg (4 vials).
  - b) Subcutaneous: 125 mg once weekly. IV loading dose is not needed.

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease, as demonstrated by improvement in joint pain, inflammation, skin lesions, etc.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Rheumatoid Arthritis (RA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Orencia is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;  
*Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND*
5. Member has tried and failed treatment with at least two preferred biologic DMARDs (see Appendix); treatment failure requires at least 12 weeks of therapy with each drug; AND
6. Member has had a negative tuberculosis (TB) test within the past 12 months.
7. **Dosage allowed/Quantity limit:**
  - a) Intravenous: Weight-based IV infusion at week 0, 2, 4, and every 4 weeks thereafter.
    - i) Less than 60 kg: 500 mg (2 vials);
    - ii) 60 to 100 kg: 750 mg (3 vials);
    - iii) More than 100 kg: 1000 mg (4 vials).
  - b) Subcutaneous: 125 mg subQ once weekly.

If a weight-based IV loading dose is needed, may administer an optional loading dose as a single IV infusion, followed by the first subcutaneous injection within one day of the infusion.

***If all the above requirements are met, the medication will be approved for 12 months.***

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## Prophylaxis for Acute Graft versus Host Disease (aGVHD)

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Orencia is prescribed by or in consultation with a hematology/oncology specialist; AND
3. Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor; AND
4. Orencia will be given in combination with a calcineurin inhibitor and methotrexate; AND
5. Antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation will be administered before Orencia, and continued for 6 months following HSCT (also consider prophylactic antivirals for Cytomegalovirus (CMV) infection/reactivation); AND
6. Member has had a negative tuberculosis (TB) test; AND
7. Member is not concomitantly on a TNF antagonist or JAK inhibitor.
8. **Dosage allowed/Quantity limit:**  
Age 6 and older: 10 mg/kg (max 1,000 mg) IV infusion on the day before transplant, followed by administration on days 5, 14, and 28 after transplantation.  
Age 2 to less than 6 years: 15 mg/kg IV infusion on the day before transplant, followed by 12 mg/kg on days 5, 14, and 28 after transplantation.

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:

1. Continued use of Orencia beyond the initial 4 dose regimen will not be authorized.

**CareSource considers Orencia (abatacept) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Orencia created. Policy SRx-0042 archived. Age adjusted for JIA. List of diagnoses considered not medically necessary added.
08/02/2017	New diagnosis of PsA added.
02/26/2019	Humira trial removed from criteria; Actemra, Cimzia, Kevzara, Olumiant, Otezla and Xeljanz added to trial agents. Clarifications entered for PsA on NSAIDs trial length. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added.

<b>11/22/2020</b>	<p>Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. Updated dosing sections.</p> <p><u>JIA</u>: Changed trials to require one non-biologic DMARD. Specified name to be pJIA. Removed 6 months of active disease and 5 or more joints involved.</p> <p><u>PsA</u>: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.).</p> <p><u>RA</u>: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.</p>
<b>01/04/2022</b>	<p>Transferred to new template.</p> <p>Added new section for aGVHD prophylaxis (also had to add “inpatient” to site of service).</p> <p>RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1. Changed second step to say at least 2 preferred biologics (previously listed specific drugs including some JAK inhibitors).</p> <p>PsA: Clarified reauthorization criteria. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Updated wording for preferred biologic trials.</p>
<b>04/01/2022</b>	Added preferred biologics appendix
<b>02/10/2023</b>	Added Amjevita to the Appendix as a preferred alternative

#### References:

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- Smolen JS, Landewé RBM, Bijlsma JWW, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
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- Watkins B, et al. Phase II trial of costimulation blockade with abatacept for prevention of acute GVHD. *J Clin Oncol*. 2021;39(17):1865–1877. doi:10.1200/JCO.20.01086
- Abatacept as GVHD Prophylaxis Phase 2. ClinicalTrials.gov identifier: NCT01743131. Updated August 4, 2021. Accessed January 4, 2022. <https://clinicaltrials.gov/ct2/show/NCT01743131>
- 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;7(2):e157-e167. doi:10.1016/S2352-3026(19)30256-X

Effective date: 04/07/2023

Revised date: 02/10/2023

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	<ul style="list-style-type: none"> <li>• Actemra (<i>requires step through Humira and Amjevita</i>)</li> <li>• Amjevita</li> <li>• Enbrel</li> <li>• Humira</li> </ul>
Approved for Juvenile Idiopathic Arthritis	<ul style="list-style-type: none"> <li>• Actemra (<i>requires step through Humira and Amjevita</i>)</li> <li>• Amjevita</li> <li>• Enbrel</li> <li>• Humira</li> </ul>
Approved for Ankylosing Spondylitis	<ul style="list-style-type: none"> <li>• Amjevita</li> <li>• Cosentyx</li> <li>• Enbrel</li> <li>• Humira</li> <li>• Rinvoq</li> </ul>
Approved for Non-radiographic Axial	<ul style="list-style-type: none"> <li>• Cimzia</li> <li>• Cosentyx</li> </ul>
Approved for Atopic Dermatitis	<ul style="list-style-type: none"> <li>• Rinvoq</li> </ul>
Approved for Psoriatic Arthritis	<ul style="list-style-type: none"> <li>• Amjevita</li> <li>• Cosentyx</li> <li>• Enbrel</li> <li>• Humira</li> <li>• Otezla</li> <li>• Skyrizi</li> <li>• Stelara</li> <li>• Tremfya</li> </ul>
Approved for Psoriasis	<ul style="list-style-type: none"> <li>• Amjevita</li> <li>• Cosentyx</li> <li>• Enbrel</li> <li>• Humira</li> <li>• Otezla</li> <li>• Skyrizi</li> <li>• Stelara</li> <li>• Tremfya</li> </ul>
Approved for Crohn's Disease	<ul style="list-style-type: none"> <li>• Amjevita</li> <li>• Humira</li> <li>• Stelara</li> </ul>
Approved for Ulcerative Colitis	<ul style="list-style-type: none"> <li>• Amjevita</li> <li>• Humira</li> <li>• Stelara</li> <li>• Rinvoq</li> </ul>