CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Orencia (abatacept)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Orencia, initially approved by the FDA in 2005, is a selective T cell costimulation modulator indicated for rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), psoriatic arthritis (PsA) and prophylaxis for acute graft versus host disease (aGVHD). It inhibits T-cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28.

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 a confirmed diagnosis of moderately to severely active pJIA; AND
4. Member has had an 8-week trial and failure of a conventional DMARD (e.g., methotrexate, leflunomide, etc.), unless not tolerated or contraindicated; AND
5. Member has had a 12-week trial and failure of **TWO** preferred biologic medications; AND
6. Member has had a negative tuberculosis (TB) test within the past 12 months.
7. **Dosage allowed/Quantity limit:**
   a) Intravenous (6 years and older only): 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 such as decreased joint swelling, decreased pain and improved quality of life.

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 2 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 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 conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Conventional DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional 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 **TWO** preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor; AND
6. Member has had a negative tuberculosis (TB) test within the past 12 months.
7. **Dosage allowed/Quantity limit:**
   a) Intravenous (adults only): weight-based dosing (see table below) on week 0, 2, 4, and every 4 weeks thereafter.

Body Weight of Adult Patient	Dose	Number of Vials[a]
Less than 60 kg	500 mg	2
60 to 100 kg	750 mg	3
More than 100 kg	1,000 mg	4

   b) Subcutaneous:
      i) Adults: 125 mg once weekly. IV loading dose is not needed.
      ii) Pediatrics: weight-based dosing (see table below) once weekly.

Body Weight of Pediatric Patient	Dose (once weekly)
10 to less than 25 kg	50 mg
25 to less than 50 kg	87.5 mg
50 kg or more	125 mg

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 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 had a 12-week trial and failure of **TWO** preferred biologic DMARDs; 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.
May administer an optional intravenous 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 transplant or hematology/oncology specialist; AND
3. Orencia is prescribed for the prophylaxis of aGVHD; AND
4. Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor; AND
5. Orencia will be given in combination with a calcineurin inhibitor and methotrexate; AND
6. 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
7. Member has had a negative tuberculosis (TB) test; AND
8. Member is not concomitantly on a biologic DMARD or JAK inhibitor.
9. **Dosage allowed/Quantity limit:**
   Age 6 years and older: 10 mg/kg (max 1,000 mg) IV infusion on the day before transplant, followed by a dose 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.

11/22/2020	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. JIA: 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. PsA: 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.). RA: 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.
01/04/2022	Transferred to new template. Added new section for aGVHD prophylaxis (also had to add "inpatient" to site of service). 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). PsA: Clarified reauthorization criteria. Edited the terminology "non-biologic" DMARD to "conventional" DMARD. Updated wording for preferred biologic trials.
11/15/2023	PsA: lowered age limit from 18 to 2 years of age and added pediatric dosing.
03/12/2024	aGVHD: Updated references. Changed "TNF antagonist" to "biologic DMARD" for excluded concomitant use. Added transplant specialist as a prescriber option. Added that the use is for aGVHD prevention.
06/14/2024	Added/removed references. pJIA: added examples of improvement of signs and symptoms into reauthorization criteria; added confirmation of diagnosis; changed trial of Enbrel and Actemra to trial of two preferred biologic medications; edited the terminology "non-biologic" DMARD to "conventional" DMARD. PsA: edited the terminology "non-biologic" DMARD to "conventional" DMARD.

References:

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479. doi:10.1038/s41584-022-00798-0 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
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Effective date: 01/01/2025
Revised date: 06/14/2024