CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Orencia (abatacept)
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 **both** Enbrel and Actemra. 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); 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; 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.

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.

References:

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2021.
2. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guidelines for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res* (Hoboken). 2019 Jun;71(6):717-734.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
4. Smolen JS, Landewé RBM, Bijlsma JWJ, 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.
5. Kremer JM, et al. Effects of Abatacept in Patients with Methotrexate-Resistant Active Rheumatoid Arthritis: A Randomized Trial. *Ann Intern Med*. 2006 Jun 20;144(12):865-76.
6. Mease PJ, et al. Efficacy and safety of abatacept, a T-cell modulator, in a randomised, double-blind, placebo controlled, phase III study in psoriatic arthritis. *Ann Rheum Dis*. 2017 Sep;76(9):1550-1558.
7. Gladman DD, Ritchlin C. Clinical manifestations and diagnosis of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
8. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 23, 2020.
9. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. *Arthritis Rheumatol*. 2016 May;68(5):1060-71.
10. Kean LS, et al. Improved overall survival of patients treated with abatacept in combination with a calcineurin inhibitor and methotrexate following 7/8 HLA-matched unrelated allogeneic hematopoietic stem cell transplantation: analysis of the Center for International Blood and Marrow Transplant Research Database. Abstract presented at: 63rd Annual Meeting of American Society of Hematology; December 13, 2021; Atlanta, GA. Session 722. Accessed January 4, 2022. https://ash.confex.com/ash/2021/webprogram/Paper150742.html
11. 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
12. Abatacept as GVHD Prophylaxis Phase 2. ClinicalTrials.gov identifier: NCT01743131. Updated August 4, 2021. Accessed January 4, 2022. https://clinicaltrials.gov/ct2/show/NCT01743131
13. 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

14. 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. doi:10.1002/art.41752

Effective date: 07/01/2022
Revised date: 01/04/2022