CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Orencia (abatacept)
BILLING CODE	J0129 (1 unit = 10 mg)—infused product Must have valid NDC for self-administered product
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Actemra, Enbrel, Cimzia, Kevzara, Olumiant and Xeljanz QUANTITY LIMIT— Infused product 100 units per 28 days Self-administered product 4 per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Orencia (abatacept) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (pJIA)

For **initial** authorization:

1. Member must be 2 years of age or older with moderately to severely active pJIA; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. 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
5. Member must have tried and failed treatment with **both** Enbrel and Actemra. Treatment failure requires at least 12 weeks of therapy with each drug.
6. **Dosage allowed:**
   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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. 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
6. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
7. **Dosage allowed:**
   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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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 with moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member must have a trial and failure of, or intolerance to methotrexate and one other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND
   Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
5. Member has tried and failed treatment with at least two of the following: Actemra, Cimzia, Enbrel, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
6. **Dosage allowed:**
   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. If a weight-based IV loading dose is needed, may administer an optional loading dose as a single IV infusion, followed by a subcutaneous injection within one day of the infusion.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Orencia (abatacept) not medically necessary for the treatment of the diseases that are not listed in this document.

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.

References:

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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, placebocontrolled, 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.

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