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PHARMACY POLICY STATEMENT
Kentucky 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.

JUVENILE IDIOPATHIC ARTHRITIS (JIA)

For **initial** authorization:

1. Member must be 2 years of age or older with moderate to severe active JIA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have least 6 months of active disease AND have five or more joints involved; AND
5. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 30 days; AND
6. Member must have tried and failed treatment with **both** Enbrel and Actemra. Treatment failure requires at least for 30 days of therapy with each drug.
7. **Dosage allowed:** Body weight of patient dose (once weekly subcutaneous): 10 to less than 25 kg – 50 mg; 25 to less than 50 kg – 87.5 mg; 50 kg or more – 125 mg. Weight less than 75 kg receive 10 mg/kg intravenously based on the patient's body weight. Pediatric patients weighing 75 kg or more should be administered Orencia following the adult intravenous dosing regimen, not to exceed a maximum dose of 1000 mg. Intravenous dosing has not been studied in patients younger than 6 years of age.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND

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3. Chart notes have been provided that show the member has shown 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.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. 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 for 30 days of therapy with each drug; AND
5. Member meets at least **one** of the following scenarios:
   a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response;
   c) Member has predominately non-axial (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 30-day trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 30-day trial of sulfasalazine or azathioprine or cyclosporine).
6. **Dosage allowed:** Body weight of patient (intravenous): less than 60 kg – 500 mg; 60 to 100 kg – 750 mg; more than 100 kg 1000 mg. Administer by subcutaneous injection once weekly with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, administer a single intravenous infusion (as per body weight categories above), followed by the first 125 mg subcutaneous injection given within a day of the intravenous infusion. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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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RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 30 days; AND
5. Member must have tried and failed treatment with at least **two** of the following: Actemra, Enbrel, Cimzia, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 30 days of therapy with each drug.
6. **Dosage allowed:** Body weight of patient (intravenous): less than 60 kg – 500 mg; 60 to 100 kg – 750 mg; more than 100 kg 1000 mg. Administer by subcutaneous injection once weekly with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, administer a single intravenous infusion (as per body weight categories above), followed by the first 125 mg subcutaneous injection given within a day of the intravenous infusion. Patients transitioning from Orencia intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown 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.

CareSource considers Orencia (abatacept) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Ankylosing spondylitis
- Crohn's disease
- Hidradenitis suppurativa
- Plaque psoriasis
- Uveitis (children/adolescents)

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.

References:

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March, 2017.
2. American College of Rheumatology. Guidelines for the management of rheumatoid arthritis: American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Arthritis Rheuma. 1996;39(5):713-723.
3. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications Vol. 65, No. 10, October 2013, pp 2499–2512.
4. 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.
5. 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.

Effective date: 04/01/2019
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