

**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
 Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

STEP  
2

Diagnosis	<input type="checkbox"/> Moderate to severely active Rheumatoid Arthritis	<input type="checkbox"/> Other (please state): _____ _____ _____
	<input type="checkbox"/> Juvenile Idiopathic Arthritis ( <i>IV formulation only</i> )	
Physician Specialty	<input type="checkbox"/> Rheumatology	<input type="checkbox"/> Other (please state): _____
	<i>There is no physician specialty requirement for Medicare Part D members</i>	
Clinical Consideration	<i>*Concomitant use of Orencia with other biologic therapy is contraindicated.</i>	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Orencia <sup>®</sup> (abatacept)	
	Strength _____	Sig _____
	Qty _____	Refills _____
<i>*Please attach all relevant medical records and test results*</i> <b>We will not process incomplete forms.</b> <b>If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b>		

STEP  
3

**I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)**

\_\_\_\_\_  
 Prescriber Signature

\_\_\_\_\_  
 Date

STEP  
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:  
 970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/09/12

## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

### Orencia™ (abatacept)

#### CLASSIFICATION

- Disease-modifying antirheumatic agent

#### DESCRIPTION

- Abatacept is a cytotoxic T lymphocyte antigen immunoglobulin (CTLA-4 Ig), a fusion protein, which consists of CTLA linked to modified heavy-chain constant region of human IgG1. It is a biological response modifier that demonstrates anti-inflammatory effects by downregulating T cell activation. Abatacept binds to CD80 and CD86 receptors on the antigen-presenting cell and prevents them from binding to CD28 on the T cell for optimal T cell activation.
- It is indicated for reducing signs and symptoms, inducing major clinical response, slowing progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA).
- It may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists. Abatacept should not be used with a TNF antagonist due to increased frequency of infections and serious infections. The safety and efficacy of abatacept concomitantly with other biologic rheumatoid arthritis agents (e.g. anakinra) have not been evaluated, and therefore, such use is not recommended.
- Clinical trials demonstrated the efficacy of abatacept as in adjunct in patients with active RA who failed methotrexate or tumor necrosis factor inhibitors. No comparative studies are available comparing abatacept to other disease modifying agents for rheumatoid arthritis.
- Abatacept plus methotrexate provided a sustained (1 year) clinical benefit in rheumatoid arthritis patients who initially had an inadequate response to methotrexate or to one or more disease-modifying, anti-rheumatic drugs, such as methotrexate or tumor necrosis factor antagonists.
- Benefits (as measured by American College Rheumatology) were maintained up to 3 years in an open-label extension study.
- Abatacept plus methotrexate was superior to methotrexate-alone in disease remission and radiographic progression in a multinational, randomized, double-blind, phase 3b study (n=509) in methotrexate-naive, early RA patients with poor prognostic factors.
- Abatacept may be given intravenously or subcutaneously. Subcutaneous abatacept was not inferior to intravenous abatacept for improving clinical response in a randomized, double-blind, double-dummy, non-inferiority study (n=1457) in patients with RA receiving background methotrexate therapy, and experiencing inadequate response.
- Abatacept is indicated for monotherapy or in combination with methotrexate for reducing signs and symptoms of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in pediatric patients 6 years and older. In a 3-part study that included an open-label extension, treatment with intravenous abatacept at a dose of 10 milligrams/kilogram/dose led to improvement in JIA symptoms in patients 6 years and older who had an inadequate response to one or more disease-modifying antirheumatic drugs.

## FORMULARY COVERAGE

Prior authorization: (required)

Good Health Formulary: Tier 6 (IV); Tier 5 (SQ)

Commercial Formulary: Tier 6 (IV and SQ)

Medicare Part D coverage: Tier 5 (IV and SQ)

## COVERAGE CRITERIA

Orencia™ (abatacept) meets the definition of **medical necessity** for the following:

- Adult Rheumatoid Arthritis (RA) that is moderate to severely active. May be used as monotherapy or concomitantly with DMARDs other than TNF antagonist to reduce signs and symptoms, induce major clinical response, slow the progression of structural damage, and improve physical function.
  - IV or SQ formulation
- Juvenile Idiopathic Arthritis as monotherapy or in combination with methotrexate for reducing signs and symptoms of moderate to severe active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years and older.
  - IV formulation only

Orencia™ (abatacept) is considered **experimental** for the following:

- Juvenile rheumatoid arthritis in children who failed treatment with at least one disease modifying anti-rheumatic drug is under investigation and not an FDA approved indication due to inconclusive evidence.
- Psoriasis vulgaris in patients with stable, treatment-resistant psoriasis. Evidence favors efficacy but is not an FDA approved indication.
- Systemic lupus erythematosus is still under investigation for the treatment and prevention of active systemic lupus erythematosus flares in combination with prednisone and is not an FDA approved indication due to inconclusive evidence.

Required Provider Specialty:

- Approval is limited to Rheumatology
- There is no physician specialty requirement for Medicare Part D members

## DOSAGE/ADMINISTRATION:

- Moderate to severe Rheumatoid Arthritis
  - **Intravenous route:** infuse over 30 minutes and repeat at 2 and 4 weeks after the first dose and then every 4 weeks thereafter
    - 500 mg for patients weighing less than 60 kg
    - 750 mg for patients weighing 60 to 100 kg
    - 1000 mg for patients weighing over 100 kg

- **Subcutaneous route:**
  - *With IV Loading Dose:*
    - The recommended subcutaneous dosing regimen of abatacept in patients following a single IV, weight-based, loading dose is 125 mg subQ within 1 day of the loading dose, followed by 125 mg subQ once weekly.
  - *Without IV Loading Dose:*
    - In patients who are unable to receive an IV infusion, abatacept 125 mg subQ weekly may be initiated without an initial IV loading dose.
  - *Transitioning from Intravenous to Subcutaneous Therapy*
    - The recommended subcutaneous dosing regimen of abatacept in patients transitioning from intravenous to subcutaneous therapy is 125 mg subQ in place of the next scheduled IV dose, followed by 125 mg subQ once weekly.
- Juvenile idiopathic arthritis (Moderate to Severe), active, polyarticular
  - **Intravenous route:** infuse over 30 minutes and repeat at 2 and 4 weeks after the first dose and then every 4 weeks thereafter
    - Patients 6 to 17 years of age weighing less than 75 kilograms: 10 milligrams/kilogram (mg/kg)
    - Patients 6 to 17 years of age weighing 75 kg to 100 kg: 750 mg
    - Patients weighing more than 100 kg: 1000 mg (maximum dose)
  - The safety and effectiveness of abatacept have not been established in pediatric patients less than 6 years of age.
  - The subQ formulation has not been studied in children.

## PRECAUTIONS:

- Concomitant use of biologic rheumatoid arthritis therapy (e.g. anakinra), tumor necrosis factor (TNF) antagonists, live vaccines, or use of live vaccines within 3 months of discontinuation of abatacept is not recommended.
- COPD increases risk for adverse effects and exacerbation of disease; monitoring recommended.
- Hepatitis B reactivation has been associated with antirheumatic therapies; screen for viral hepatitis before initiating abatacept therapy.
- Hypersensitivity reactions, including anaphylaxis or anaphylactoid reactions, have been reported
- Serious infections (e.g. sepsis and pneumonia), including fatalities, have been reported, especially with concomitant immunosuppressant therapy; use caution in patients with a history of recurrent infections, underlying conditions with predisposition for infections, or chronic, latent, or localized infections; discontinue therapy if a serious infection develops.
- Tuberculosis (TB), active or latent; initiate treatment for TB prior to initiating abatacept therapy.

## Billing/Coding information

### HCPCS Code:

J0129	Injection, abatacept, 10mg
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### Associated ICD-9 Coding:

714.0	Rheumatoid Arthritis
714.2	Other rheumatoid arthritis with visceral or systemic involvement
714.30	Polyarticular Juvenile Rheumatoid Arthritis

## COST

AWP (November 2011)

- \$26.89/ 10 mg
- \$672.25/ 250 mg vial
- \$596.54/ 125mg SQ syringe

## COMMITTEE APPROVAL:

- March 2006

## GUIDELINE UPDATE INFORMATION:

December 26, 2005	FDA approves Orencia for Rheumatoid Arthritis
March 16, 2006	Prior Authorization creation
April 17, 2008	FDA approves new indication for the treatment of polyarticular juvenile idiopathic arthritis
August 23, 2011	FDA approval of Subcutaneous Formulation
November 3, 2011	Coverage policy creation

## REFERENCES:

- DRUGDEX®, accessed 11/3/11
- Product Information: Orencia™ (abatacept) for IV injection, for subcutaneous use. Bristol-Myers Squibb, Princeton, NJ 2011.