

Origination Date: 4/06	Revision Date(s): 4/07, 4/08, 4/09, 3/11
Developed By: Medical Criteria Committee	

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ODS RX ^{1.0} <input type="checkbox"/>	ODS RX ^{2.0} <input checked="" type="checkbox"/>	OEBB <input checked="" type="checkbox"/>	OHP <input type="checkbox"/>
NON-SPECIALTY <input type="checkbox"/>	SPECIALTY <input checked="" type="checkbox"/>		
PA <input checked="" type="checkbox"/>	QLL <input type="checkbox"/>	STEP THERAPY <input type="checkbox"/>	

PURPOSE: To ensure the appropriate and safe use of Orencia for FDA approved indications.

DESCRIPTION: Orencia is a recombinant soluble fusion protein classified as a costimulation modulator. Orencia inhibits T cell activation by binding to CD80 and CD86, which blocks the interaction with CD28. This in-turn prevents full activation of the T lymphocytes attenuating the inflammatory cascade at earlier stages.

INDICATION:

- Adult rheumatoid arthritis (RA):
 - For reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. Abatacept may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.
- Juvenile idiopathic arthritis:
 - For reducing signs and symptoms in children 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Abatacept may be used as monotherapy or concomitantly with methotrexate.

PRODUCT AVAILABILITY:

- Orencia (Abatacept)
 - 250 mg in a 15 mL vial

QUANTITY LIMIT: The following quantity limits apply to approved Prior Authorizations:

- 16 vials during initial 60 days of approval and 4 vials per 30 day period thereafter if renewal is approved.
 - Orencia is dosed at 2 and 4 weeks following the initial infusion, and then once every 4 weeks thereafter.

GUIDELINES FOR USE:

- 1) Is Orencia prescribed by a rheumatologist?
 - a) If yes, go to #2
 - b) If no, forward to clinical for review
- 2) Has the patient had a NEGATIVE tuberculin skin test, or if positive, has treatment for latent TB been initiated prior to Orencia therapy?
 - a) If yes, go to #3
 - b) If no, forward to clinical for review
- 3) Will the patient be using Orencia with Humira®, Remicade®, Enbrel®, Rituxan® or Kineret®?

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- a) If yes, forward to clinical for review
 - b) If no, go to #4 for induction therapy with Orencia
 - c) If no, go to #6 for maintenance therapy with Orencia
- 4) Is the patient being treated for moderately- to severely-active rheumatoid arthritis with documented evidence of at least four of the following for at least 6 weeks duration:
- i) Prolonged morning stiffness in the joints (≥ 45 minutes duration)
 - ii) Arthritis of 3 or more joint areas: wrist, elbow, knee, subtalar, MTP or hands (MCP or PIP)
 - iii) Arthritis of hand joints
 - iv) Symmetric arthritis
 - v) Rheumatoid nodules under the skin
 - vi) Elevated levels of serum rheumatoid factor
 - vii) Radiographic changes in the joints
- a) If yes, go to #5
 - b) If no, forward to clinical for review
- 5) Has the patient met at least two of the following criteria:
- i) Documented failure of optimal dosing/adequate duration of methotrexate
 - ii) Documented failure of optimal dosing/adequate duration of a DMARD other than methotrexate
 - iii) Contraindication or intolerance to methotrexate
 - iv) Documented failure of Humira, Enbrel or Remicade
- a) If yes, approved for 3 months induction therapy
 - b) If no, forward to clinical for review

RENEWAL CRITERIA:

- 6) Has the patient had:
- i) $\geq 20\%$ improvement in the number of tender joints AND
 - ii) $\geq 20\%$ improvement in the number of swollen joints AND
 - iii) $\geq 20\%$ improvement in three of the following five measures:
 - (1) Pain
 - (2) Global assessment of disease activity by the physician
 - (3) Global assessments of disease activity by the patient
 - (4) Patient assessment of physical function
 - (5) Levels of acute phase reactant (ESR or CRP)
 - iv) OR achieved an equivalent therapeutic response as indicated by scoring using the DAS28, SDAI or CDAI indices.
- a) If yes, approved for 12 months for maintenance therapy
 - b) If no, forward to clinical for review

Special Instructions

Clinical Information:

Dosing for RA

- 500 mg if weight <60 kg (132 lbs)
750 mg if 60 to 100 kg (132 to 220 lbs)
1 g if >100 kg (> 220 lbs)
Administered as a 30 minute IV infusion at 0, 2, and 4 weeks then every 4 weeks thereafter.

Pregnancy Category: C

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Trial Data

- Infections occurred in 54% of Orencia-treated pts and 48% of placebo-treated pts.
- Serious infections occurred in 3% of Orencia-treated pts and 1.9% in placebo-treated pts.
- Pts receiving concomitant Orencia and TNF antagonists experienced more infections (63%) and serious infections (4.4%) compared to pts treated with only TNF antagonists (43% and 0.8% respectively).

Precautions

- Before initiating Orencia therapy, pts should be screened for latent tuberculosis (TB) with a skin test. Patients testing positive during TB screening should be treated prior to therapy with Orencia.
- COPD pts treated with Orencia developed adverse events more frequently than those treated with placebo and thus should be monitored for worsening of respiratory status.

Storage

- Orencia must be refrigerated at 2°C to 8°C (36°F to 46°F) before use. Must be used within 24 hours of reconstitution.
- Once diluted, may be stored at room temp or refrigerated before use.

Adverse Events Seen in Trials:

- The most commonly reported adverse events (occurred in $\geq 10\%$ of pts with Orencia compared to placebo) were headache, upper respiratory tract infection, nasopharyngitis and nausea.