Orencia (abatacept)
Policy Number: C10420-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
09/2013	02/13/2019	02/13/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J0129-inj, abatacept, 10mg	RxPA	Q1 2019

PRODUCTS AFFECTED:
Orencia

DRUG CLASS:
Selective Costimulation Modulators

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

PLACE OF SERVICE:
Specialty Pharmacy or Buy and Bill

AVAILABLE DOSAGE FORMS:
Orencia 250mg IV solution, Orencia ClickJect 125mg/ml, Orencia 50mg/0.4ml PFS, Orencia 87.5mg/0.7ml PFS, Orencia SOSY 125MG/ML

FDA-APPROVED USES: indicated for: moderately to severely active rheumatoid arthritis (RA) in adults. ORENCIA may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists and moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older. ORENCIA may be used as monotherapy or concomitantly with methotrexate

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: moderately to severely active rheumatoid arthritis (RA) and moderately to severely active polyarticular juvenile idiopathic arthritis

REQUIRED MEDICAL INFORMATION:
FOR ALL INDICATIONS:

1. (a) Negative TB test within the last 12 months for initial and continuation of therapy requests
   OR
   (b) If member tests positive for latent TB, there must be documentation showing member completed a treatment course for TB OR that member has been cleared by an infectious disease specialist to begin treatment
   OR
   (c) For members who have tested positive for latent TB and have been treated, a negative chest x-ray is required every 12 months
   AND
2. Documentation of baseline liver functions, platelet count, absolute neutrophil count (ANC)

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:
   1. Documentation of moderate to severe rheumatoid arthritis diagnosis
      AND
   2. Prescriber has assessed baseline disease severity utilizing an objective measure/tool
      AND
   3. (a) Patient tried, failed or has a contraindication or intolerance to methotrexate, as determined by the prescribing physician; or Patient is concurrently receiving MTX AND Patient has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months, [this includes patients who have tried other biologic DMARDs for at least 3 months]
      (NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD)
      OR
      (b) Patient has early RA (defined as disease duration of < 6 months) with at least one of the following features of poor prognosis: functional limitation (e.g., based on Health Assessment Questionnaire Disability Index [HAQ-DI] score); extra articular disease such as rheumatoid nodules, RA vasculitis, or Felty's syndrome; positive rheumatoid factor or anti-cyclic citrullinated protein (anti-CCP) antibodies; or bony erosions by radiograph;
      AND
   4. IF THIS IS A NON-FORMULARY PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s)

B. JUVENILE IDIOPATHIC ARTHRITIS (ACTIVE SYSTEMIC AND ACTIVE POLYARTICULAR):
   1. Member must have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) or polyarticular juvenile idiopathic arthritis (PJIA) in children 2 years of age or older
      AND
   2. Prescriber has assessed baseline disease severity utilizing an objective measure/tool
      AND
   3. Documentation of drug failure or serious side effects to an adequate trial (12 weeks) of glucocorticoids, methotrexate, anakinra or leflunomide
      AND
   4. IF THIS IS A NON-FORMULARY PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s)

C. PSORIATIC ARTHRITIS (PsA):
   1. Documentation of active and progressive PsA, evidenced by one (1) of the following: ≥3 swollen joints and 3 tender joints, Axial involvement that has not responded to NSAIDs, A high Psoriasis Area and Severity Index (PASI) score and a severely affected quality of life, Enthesitis (inflammation of the insertion of tendons or ligaments into bone) and dactylitis (inflammation of the whole digit) that has not responded to NSAIDs and locally injected glucocorticoids, and for which there is no evidence for non-biologic DMARD efficacy
      AND

2. (a) Treatment failure with or a clinical contraindication to a minimum 3-month trial of two (2) of the following DMARDs (standard target doses must have been taken for ≥2 months): Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
   OR
   (b) Documentation of predominant axial PsA and Treatment failure with NSAIDs (does NOT require trial of DMARD therapy)
   OR
   (b) Documentation of peripheral arthritis and Documentation of treatment failure with or a clinical contraindication to a minimum 3-month trial of one (1) of the following DMARDs (standard target doses must have been taken for ≥2 months): Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
   AND
3. IF THIS IS A NON-FORMULARY PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s)

DURATION OF APPROVAL: Initial authorization: 6 months. Continuation of therapy: 12 months

QUANTITY: Intravenous: 4 vials per 28 days * (during initiation of therapy an additional 4 vials may be approved in the first 28 days of treatment). Subcutaneous: 4 syringes/autojectors per 28 days

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with a board-certified rheumatologist

AGE RESTRICTIONS: Subcutaneous injection for 2 years of age and older; Intravenous administration for 6 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS AND JUVENILE IDIOPATHIC ARTHRITIS (ACTIVE SYSTEMIC AND ACTIVE POLYARTICULAR :
   1. Patient continues to meet initial criteria
      AND
   2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: neutropenia (absolute neutrophil count (ANC) below 1000 per mm3), thrombocytopenia (platelet count below 100,000 per mm3), hepatotoxicity (ALT or AST above 3-5 times the upper limit of normal), gastrointestinal perforation, severe hypersensitivity reactions, demyelinating disorders, etc.
      AND
   3. Patient is receiving ongoing monitoring for presence of TB or other active infections;
      AND
   4. (a) Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a ≥20% improvement on the American College of Rheumatology-20 (ACR20) criteria]
      OR

(b) Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables]

B. PSORIATIC ARTHRITIS (PsA):
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
      AND
   2. Documentation of no intolerable adverse effects or drug toxicity
      AND
   3. Documentation of a positive response to treatment, evidenced by at least one (1) of the following: Demonstrated stabilization or improvement in joint pain and inflammation and reduction in skin lesions, Improvement in the number of tender joints, Improvement in the number of swollen joints, OR Improvement in three (3) of the following five (5) measures: Pain, Global assessment of disease activity by the physician, Global assessment of disease activity by the patient, Patient assessment of physical function, Levels of acute phase reactant(s) [CRP (C-reactive protein) and ESR (erythrocyte sedimentation rate)]

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Orencia (abatacept) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Orencia has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions: Ankylosing Spondylitis (AS), Concurrent Use with a Biologic or with a Targeted Synthetic DMARD, Inflammatory Bowel Disease (i.e., Crohn's Disease [CD], Ulcerative Colitis [UC]) or Psoriasis.

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND:
Abatacept (Orencia®) is a soluble recombinant fusion protein, selective T cell costimulation modulator that inhibits T cell activation. The drug consists of human cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) linked to a modified Fc portion of human immunoglobulin G1 (IgG1). Abatacept selectively inhibits T-cell activation and stimulation by binding to CD80 and CD86 on antigen-presenting cells (APC), thereby preventing the binding of CD80 or CD86 to CD28 on T cells

APPENDIX:
OBJECTIVE MEASURES FOR RA:
[Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Patient Activity Scale (PAS or PAS-II), Routine Assessment of Patient Index Data with 3 measures, Simplified Disease Activity Index (SDAI)]
OBJECTIVE MEASURES FOR PJIA:
Global Arthritis Score (GAS), Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS), Disease Activity Score based on 28-joint evaluation (DAS28), Simple Disease Activity Index (SDAI), Health Assessment Questionnaire disability index (HAQ-DI), Visual Analogue Scale (VAS), Likert

scales of global response or pain by the patient or global response by the physician, Joint tenderness and/or swelling counts, Laboratory data

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