Orencia (abatacept)
Policy Number: C10420-A

CRITERIA EFFECTIVE DATES:

<table>
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<tr>
<th>ORIGINAL EFFECTIVE DATE</th>
<th>LAST REVIEWED DATE</th>
<th>NEXT REVIEW DATE</th>
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<tr>
<td>9/1/2013</td>
<td>8/26/2020</td>
<td>8/26/2021</td>
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J CODE | TYPE OF CRITERIA | LAST P&T APPROVAL/VERSION |
J0129-injection, abatacept, 10mg | RxPA | Q4 2020 20201028C10420-A |

PRODUCTS AFFECTED:
Orencia (abatacept)

DRUG CLASS:
Selective Costimulation Modulators

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

PLACE OF SERVICE:
Specialty Pharmacy or Buy and Bill
The recommendation is that medications in this policy will be for pharmacy benefit coverage and the IV infusion products administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider’s office, free-standing ambulatory infusion center) and the Pre-Filled Syringe product for self-administered.

AVAILABLE DOSAGE FORMS:
Orencia 125mg/1ml Vial IV powder for solution, Orencia ClickJect 125mg/ml Auto-Injector, Orencia Prefilled Syringe 50mg/0.4ml, 87.5mg/0.7ml, 125mg/ml

FDA-APPROVED USES:
indicated for: moderately to severely active rheumatoid arthritis (RA) in adults, moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. ORENCIA may be used as monotherapy or concomitantly with methotrexate, active adult psoriatic arthritis.

Important Limitations of Use: should not be given concomitantly with TNF antagonists

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, psoriatic 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 with Ocrevus
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. Member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
AND
3. Member is not on concurrent treatment or will be used in combination with other TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib)
AND
4. Member does not have an active infection, including clinically important localized infections
AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED 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) [DOCUMENTATION REQUIRED]

A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:
   1. Documentation of moderate to severe rheumatoid arthritis diagnosis
      AND
   2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal
      AND
   3. (a) Member is concurrently receiving methotrexate
      OR
      (b) Member has tried, failed or has an FDA labeled contraindication or intolerance to methotrexate, as determined by the prescribing physician AND Member has tried one additional disease-modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months
      (NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the Member has already had 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) Member 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

B. JUVENILE IDIOPATHIC ARTHRITIS (ACTIVE POLYARTICULAR):
   1. Prescriber attests to 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 attests that the member has been 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 [DOCUMENTATION REQUIRED]
Prior Authorization Criteria

C. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis
   AND
2. (a) Documented treatment failure with or FDA labeled contraindication to a minimum 3-month trial of ONE of the following DMARDs (standard target doses must have been taken for ≥2 months): Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
   OR
   (b) Documentation of member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease
   OR
   (c) Documentation of member has severe psoriasis [PASI >12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

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

CONTINUATION OF THERAPY:
A. ALL INDICATIONS:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member 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 positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms.

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), Member Activity Scale (PAS or PAS-II), Routine Assessment of Member 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 member or global response by the physician, Joint tenderness and/or swelling counts, Laboratory data

Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:
1. The patient is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The patient exhibits physical or cognitive impairment and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the patient's first dose of the medication or it is being re-initiated after at least 12 months*
5. The patient has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at a non-hospital facility-based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

Note: a hospital outpatient setting, or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, member records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may
deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES: