Effective Date: 09/01/2013
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Next Review Due By: 01/2023
Policy Number: C10420-A

Orencia (abatacept)

PRODUCTS AFFECTED

Orencia (abatacept)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be readin its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and themember are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

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 andabuse prevention processes. Documentation required may include, but is not limited to, patient 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 doesnot 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

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

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within thelast 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formularypreferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

FOR ALL INDICATIONS:

1. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests
   OR
   (b) For members who have a positive test for latent TB, provider documents member

has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Prescriber attests member has been evaluated and screened for the presence ofhepatitis 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) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
4. Prescriber attests 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/PDLalternatives 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 oneadditional 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 canbe 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
(c) Member has early RA (defined as disease duration of < 6 months) with at least oneof 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 (SYSTEMIC AND POLYARTICULAR):
1. Prescriber attests to a diagnosis of systemic juvenile idiopathic arthritis (SJIA) or polyarticular juvenile idiopathic arthritis (PJIA) in children 2 yearsof age or older (for subcutaneous) or 6 years of age or older (for intravenous)
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) FOR SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS: Documentation of drug failure or serious side effects to an adequate trial (up to 12 weeks) of TWO of the following: NSAIDs, glucocorticoids, methotrexate, leflunomide, anakinra (Kineret), canakinumab (Ilaris), or tocilizumab (Actemra)

(b) FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of ≥1 of the following: Methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, leflunomide

C. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis
   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) 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]

D. ACUTE GRAFT VERSUS HOST DISEASE PROPHYLAXIS:

1. Documentation member is scheduled for a hematopoietic stem cell transplant (HSCT) from a matched or 1 allele- mismatched unrelated donor
   AND
2. Prescriber attests Orencia will be used concurrently with a calcineurin inhibitor and methotrexate

CONTINUATION OF THERAPY:

A. ALL INDICATIONS (EXCEPT ACUTE GRAFT VERSUS HOST DISEASE):

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 tothe 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 activityand/or improvements in the condition's signs and symptoms.
   AND
4. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requestsOR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also requiredevery 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months. Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

For Psoriatic Arthritis: Prescribed by or in consultation with a board-certified rheumatologist or dermatologist
For Prophylaxis of Acute Graft versus Host Disease: Prescribed by or in consultation with board-certified transplant or hematologist/oncologist specialist
All other indications: Prescribed by or in consultation with a board-certified rheumatologist [If prescribed in consultation, consultation notes must be submitted within initialrequest and reauthorization requests]

AGE RESTRICTIONS:

Psoriatic arthritis, rheumatoid arthritis: 18 years and older
Juvenile idiopathic arthritis: Subcutaneous injection for 2 years of age and older; Intravenous administration for 6 years of age and older
Prophylaxis of acute graft versus host disease: 2 years of age and older
NOTE: The autoinjector has not been studied in patients under 18 years of age.

QUANTITY:

Rheumatoid Arthritis, Psoriatic Arthritis:
Intravenous: <60 kg: 500 mg (2 vials), 60 kg to 100 kg: 750 mg (3 vials), more than 100 kg: 1000 mg (4 vials) every 28 days (Following the initial intravenous infusion, administer as an intravenous infusion at 2 and 4 weeks and every 4 weeks thereafter).Subcutaneous: 125 mg once weekly (4 syringes/autojectors per 28 days)

Polyarticular Juvenile Idiopathic Arthritis:
Intravenous: <75 kg: 10 mg/kg, 75 kg or greater: follow adult IV dosing regimen not to exceed 1000 mg.
Administer infusions at 2 and 4 weeks and every 4 weeks thereafter.
(Following the initial intravenous infusion, administer as an intravenous infusion at 2 and 4 weeks and every 4 weeks thereafter).
Subcutaneous: 10 to less than 25 kg: 50 mg weekly, 25 to less than 50 kg: 87.5 mg weekly, 50 kg or more: 125 mg weekly

Intravenous Use for prophylaxis of acute graft versus host disease;
For patients 6 years and older, 10 mg/kg dose (maximum dose 1,000 mg) on the day before transplantation, followed by a dose on Day 5, 14, and 28 after transplant
For patients 2 to less than 6 years old, administer a 15 mg/kg dose on the day before transplantation, followed by a 12 mg/kg dose on Day 5, 14, and 28 after transplant

Maximum Quantity Limits –

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

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Healthcare Site of Care program.

The recommendation is that injectable medications in this policy will be for pharmacybenefit coverage and patient self-administered.

Note: Site of Care Utilization Management Policy applies for Orencia (abatacept) intravenous. For information on site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

DRUG CLASS:
Selective Costimulation Modulators

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,
- active adult psoriatic arthritis.
- the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

Limitations of Use: Concomitant use of ORENCIA with other immunosuppressives [e.g., biologic disease- modifying antirheumatic drugs (bDMARDS), Janus kinase (JAK) inhibitors] is not recommended

COMPENDIAL APPROVED OFF-LABELED USES:
Systemic juvenile idiopathic arthritis

APPENDIX

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

BACKGROUND AND OTHER CONSIDERATIONS

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 Tcells

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 witha 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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0129	Injection, abatacept, 10mg

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

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