Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 11/07/2019

Orencia® (abatacept)

FDA approval: December 23, 2005
HCPCS: J0129
Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of intravenous or subcutaneous Orencia for rheumatoid arthritis is provided when all the following are met:
   a. Prescribed by or in consultation with a rheumatologist
   AND
   b. Diagnosis of rheumatoid arthritis (RA) in patients age 18 and older
   AND
   c. Treatment with one disease modifying antirheumatic drug (DMARD) (must be methotrexate unless contraindicated or not tolerated based on clinical documentation) is ineffective after at least 3 months trial, except if contraindicated or not tolerated based on clinical documentation. (Examples of oral DMARDS include: methotrexate, sulfasalazine, hydroxychloroquine)
   AND
   d. Should not be used in combination with a TNF antagonist
   AND
   e. Exception will be considered based on the following factors (as recommended by the ACR):
      i. Disease activity level
      ii. Time of diagnosis
         1. Early RA defined as less than 6 month
         2. Established > 6 month ago
      iii. Poor prognosis status
         1. Presence of 1 or more of the following features:
            a) Functional limitation (e.g. HAQ DI or similar valid tools)
            b) Extraarticular disease (e.g. presence of rheumatoid nodules, RA vasculitis, Felty’s syndrome)
            c) Positive rheumatoid factor or anti–cyclic citrullinated peptide antibodies, or bony erosions by radiograph
B. Coverage of intravenous Orencia is provided for juvenile idiopathic arthritis (JIA) in pediatric patients 6 years of age and older or subcutaneous injection for patients 2 years of age and older when all the following are met:
   a. Prescribed by or in consultation with a rheumatologist
   AND
   b. Diagnosis of juvenile idiopathic arthritis
   AND
   c. Treatment with one oral DMARD e.g. methotrexate or leflunomide is ineffective after at least 3 months trial, except if contraindicated or not tolerated based on clinical documentation.

C. Coverage of intravenous or subcutaneous Orencia for psoriatic arthritis is provided when all the following are met:
   a. Prescribed by or in consultation with a dermatologist/rheumatologist
   AND
   b. Diagnosis of psoriatic arthritis (PsA) in patients age 18 and older
   AND
   c. Treatment with one disease modifying antirheumatic drug (DMARD) (must be methotrexate unless contraindicated or not tolerated based on clinical documentation) is ineffective after at least 3 months trial, except if contraindicated or not tolerated based on clinical documentation. (Examples of oral DMARDS include: methotrexate, sulfasalazine, hydroxychloroquine)
   AND
   d. Should not be used in combination with a TNF antagonist

D. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management drug list and/or BCBSM/BCN prior authorization and step therapy documents

E. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: FDA approved dosing
   b. Initial Authorization Period: 6 months
   c. Renewal Authorization Period: 1 year
   d. Renewal criteria: RA only
      i. Continuation of coverage will be provided at 12 month intervals
      ii. Continued approval will require submission of progress notes demonstrating clinical response measured as improvement in 3 of any 6 variables below compared to baseline, with worsening in no more than 1 of the remaining:
         1. Physician global assessment
         2. Patient global assessment
         3. Number of joints with active arthritis
         4. Number of joints with limitation of movement
         5. Erythrocyte sedimentation rate (ESR)
         6. Functional ability (health assessment questionnaire-HAQ)
   e. Renewal criteria: JIA only
      i. Continuation of coverage will be provided at 12 month intervals
      ii. Continuation of coverage requires documentation of improvement in 3 of any 6 core outcome variables compared to baseline, with worsening in no more than 1 of the remaining variables. Core outcome variables consist of:
         1. Physician global assessment
         2. Parent per patient global assessment
         3. Number of joints with active arthritis
         4. Number of joints with limitation of movement
         5. Erythrocyte sedimentation rate (ESR)
         6. Functional ability (childhood health assessment questionnaire-CHAQ)
f. Renewal criteria: PsA only
   i. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective

F. Orencia is considered investigational when used for all other conditions, including but not limited to:
   a. When coverage criteria is not met
   b. In combination with other biologics

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. FDA approved indication/Diagnosis
   a. Moderately to severely active Rheumatoid in adults alone or in combination with DMARDs (non-TNF antagonists)
   b. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older and older or subcutaneous injection for patients 2 years of age and older alone or in combination with methotrexate
   c. Treatment of active psoriatic arthritis in adults
   d. Limitation: Should not be used in combination with TNF antagonists

*Please refer to most recent prescribing information.
www.orenciahcp.com

B. Background Information
   a. Rheumatoid arthritis (RA)
      i. A multisystem, autoimmune disease of unknown origin that primarily affects the lining of the joints (synovium)
      ii. Chronic inflammation (synovitis) characteristically involves the peripheral joints in a symmetric distribution and leads to cartilage damage and bone erosion
      iii. Systemic complications include cardiovascular and pulmonary disorders and increased risk of lymphoma
      iv. There are many treatments for rheumatoid arthritis that are effective, have known long-term safety profiles, and are recommended by national treatment guidelines
      v. When a systemic medication therapy is needed to manage one of the rheumatic disorders, oral therapies are usually the best value
   b. Juvenile idiopathic arthritis (JIA)
      i. The most common type of arthritis in children
      ii. JIA was previously called juvenile rheumatoid arthritis (JRA)
      iii. There are six JIA subtypes:
          1. Systemic onset JIA
          2. Oligoarticular JIA
          3. Polyarticular JIA
          4. Juvenile psoriatic arthritis
          5. Enthesitis related JIA
          6. Undifferentiated arthritis.
      iv. JIA may involve one or many joints, and cause other symptoms such as fevers, rash and/or eye inflammation

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v. Symptoms seen in children with JIA may include:
   1. Arthritis present for at least 6 weeks
   2. Morning stiffness and arthralgias during the day
   3. Joint pain involving one or more joints
   4. Spiking fevers
   5. Evanescent rash on the trunk and extremities
   6. Psoriasis or more subtle dermatologic manifestations

vi. The ACR recommendations for the treatment of JIA address patients with and without active systemic features of arthritis and varying degrees of synovitis

vii. These recommendations note that Kineret may be used as initial therapy for patients with systemic involvement and a MD global of ≥5 irrespective of active joint involvement

viii. Other therapies mentioned in the guidelines, include Actemra, Ilaris, Orencia, and TNF blockers

ix. In all cases, the specific recommendations vary depending on the clinical situation

c. Psoriatic Arthritis (PsA)
   i. A chronic inflammatory disease often associated with psoriasis
   ii. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches
   iii. These patches, called plaques, may appear anywhere on the body
   iv. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50
   v. PsA causes pain, stiffness, and swelling in and around the joints
   vi. If not properly treated, progressive joint damage may occur
   vii. Treatment options include NSAIDS, DMARDs, and anti-TNF biologic agents
   viii. If PsA does not respond to the initial treatment [NSAIDs, DMARDs (sulfasalazine, methotrexate, cyclosporine, and leflunomide)] as monotherapy, combination therapy may be used
   ix. Hydroxychloroquine should be avoided due to exacerbation of psoriasis
   x. Anti-TNF agents may be utilized when initial treatment has been ineffective
   xi. Anti-TNF agents approved for PsA include: Humira, Enbrel, Remicade, Cimzia and Simponi.

C. Efficacy

*Please refer to most recent prescribing information.

D. Medication Safety Considerations

Boxed Warning: No

*Please refer to most recent prescribing information.

E. Dosing and administration

*Please refer to most recent prescribing information.

F. How supplied

   a. 250 mg/15 mL vial

References:

3. Francesco et al. Methods used to assess remission and low disease activity in rheumatoid arthritis. Autoimmunity

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4. Express Scripts® Clinical Summary of Inflammatory Conditions, Rheumatoid Arthritis and Juvenile Idiopathic Arthritis- Oral agents, Infused biologics and Non-Tumor Necrosis Factor (TNF) biologics. Date Revised March 2016
8. Long-term safety, efficacy, and quality of life in patients with juvenile idiopathic arthritis treated with intravenous abatacept for up to seven years. Arthritis & Rheumatology 2015 Oct;67(10):2759-70
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<td>2.0</td>
<td>Effective Date: 11/07/2019</td>
<td>Annual Review of Medical Policy</td>
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<tr>
<td>1.9</td>
<td>Effective Date: 11/01/2018</td>
<td>Added trial of all preferred drugs to apply to all indications</td>
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<td>1.8</td>
<td>Effective Date: 10/01/2018</td>
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| 1.7 | Effective Date: 08/09/2018 | Updated language to include preferred infliximab product |
| 1.6 | Effective Date: 11/09/2017 | SQ approval for 2 years of age for JIA and New FDA approval for PsA |
| 1.5 | Effective Date: 07/05/2017 | PA added to MAPPO                                        |

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| 1.4 | Effective Date: 03/23/2017 | New coverage criteria for biologics that treat rheumatoid conditions |
| 1.3 | Effective Date: 11/10/2016 | New criteria document: Expanded criteria for JIA |
| 1.2 | Effective Date: 07/01/2016 | PA added to BCN                                                   |

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| 1.1 | Effective Date: 05/05/2016 | Criteria update |
| 1.0 | Effective Date: 01/22/2013 | PA added to BCBS |

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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

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