Blue Cross Blue Shield Blue Care Network of Michigan

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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.

RETIRED
Effective Date: 04/16/2022

Tanezumab

FDA approval: 2nd Quarter 2021
HCPCS: J3590
Benefit: Medical

Policy:

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

A. Coverage of the requested drug is provided when all the following are met:
   a. Age ≥ 18 years old
   b. Diagnosis of moderate to severe osteoarthritis of the knee or hip with a Kellgren-Lawrence grade 2 or greater and radiographic confirmation
   c. Prescribed by or in consultation with a rheumatologist or orthopedic surgeon
   d. Inadequate response to TWO or more of the following:
      i. Resistance exercise (such as structured weightlifting or resistance band program) or cardiovascular exercise (such as walking, biking, stationary bike, or aquatic exercises)
      ii. Weight reduction (in those that are overweight or obese defined as a BMI of 25 or greater) by 5% from baseline
      iii. Utilizing durable medical equipment (such as: walking aids, tibiofemoral knee braces, kinesiotaping)
      iv. Physical therapy or occupational therapy
   e. Trial and failure of ALL of the following unless contraindicated or clinically significant adverse events are experienced:
      i. For osteoarthritis of the knee:
         1. Oral non-steroidal anti-inflammatory drug (NSAID) at maximal therapeutic dosage
            a) Oral NSAID not required if the member is at least 65 years of age or under 65 years of age and unable to take an oral NSAID
         2. Topical NSAID
         3. Intra-articular corticosteroid injection
            a) Treatment failure is defined as any of the following:
               - Inadequate pain relief
               - Frequent need for continued rescue doses of NSAIDs
               - Inability to increase activity levels or need to decrease activity levels

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- Adequate pain relief but experienced steroid-induced hyperglycemia

ii. For osteoarthritis of the hip:
1. Oral non-steroidal anti-inflammatory drug (NSAID) at maximal therapeutic dosage
a) Oral NSAID not required if the member is at least 65 years of age or under 65 years of age and unable to take an oral NSAID
2. Intra-articular corticosteroid injection
a) Treatment failure is defined as any of the following:
- Inadequate pain relief
- Frequent need for continued rescue doses of NSAIDs
- Inability to increase activity levels or need to decrease activity levels
- Adequate pain relief but experienced steroid-induced hyperglycemia

f. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the BCBSM/BCN medical utilization management drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
a. Quantity limit: Align with FDA recommended dosing
b. Authorization period: 6 months
c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***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**

**Please refer to most recent prescribing information.*

B. **Background Information**

a. Osteoarthritis (OA) is a chronic condition affecting more than 30 million people in the United States. It is the most common form of arthritis, frequently affecting the hands, hips, and knees. The breakdown of cartilage within the joint leads to changes in the underlying bone that progressively worsen and contribute to joint pain, stiffness, swelling, and limited function and mobility ultimately impacting patient morbidity and quality of life.

b. The American College of Rheumatology (ACR) 2019 OA guideline and the Osteoarthritis Society International (OASI) 2019 OA guideline recommend a number of pharmacologic agents for OA management. Oral NSAIDs, topical NSAIDs, acetaminophen, duloxetine, tramadol, intra-articular corticosteroid injections, and hyaluronic acid injections are available treatment options recommended to varying degrees and under varying circumstances within the guidelines. The choice of therapy should be individualized to the patient based on efficacy, safety profile, comorbidities, preference, and cost. Oral NSAIDs remain the mainstay of OA management though the safety profile may preclude some patients from their use; topical NSAIDs are a highly recommended alternative to oral and primarily utilized for knee OA.

C. **Efficacy**

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**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

**Please refer to most recent prescribing information.*

E. **Dosing and administration**

**Please refer to most recent prescribing information.*

F. **How supplied**

**Please refer to most recent prescribing information.*

References:

1. Kolasinski SL, Neogi T, et al. 2019 American College of Rheumatology/ Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip and Knee. Arthritis Care & Research. February 2020;72(2):149-162.
2. Bannuru RR, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis and Cartilage. 2019:27:1578-1589.
3. Schnitzer TJ, et al. Effect of tanezumab on joint pain, physical function, and patient global assessment of osteoarthritis among patients with osteoarthritis of the hip or knee. JAMA. 2019;322(1):37-48.
4. Barenbam F, et al. Subcutaneous tanezumab for osteoarthritis of the hip or knee: efficacy and safety results from a 24-week randomized phase III study with a 24-week follow-up period. Ann Rheum Dis 2020; 79: 800-810.
5. Hochberg MC, et al. Subcutaneous tanezumab vs NSAID for the treatment of osteoarthritis: efficacy and general safety results from a randomized, double-blind, active-controlled, 80-week, Phase-3 study [abstract]. Arthritis Rheumatol. 2019; 71 (suppl 10).

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.1</td><td>Effective Date: 04/16/2022</td><td>Retiring Tanezumab policy.</td></tr>
<tr><td>1.0</td><td>Effective Date: 04/08/2021</td><td>Preliminary drug review
<table>
<tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr>
<tr><td>BCBS</td><td>No</td></tr>
<tr><td>BCN</td><td>No</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
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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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