Zilretta® (Triamcinolone Acetonide Extended-Release Injectable Suspension) (for Kentucky Only)

Policy Number: CSKYD0229.05
Effective Date: December 1, 2024

Instructions for Use

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Related Policies

None

Application

This Medical Benefit Drug Policy only applies to the state of Kentucky.

Coverage Rationale

Zilretta® is proven and medically necessary for the treatment of osteoarthritis pain of the knee when all of the following criteria are met:

- Diagnosis of osteoarthritis pain of the knee; **and**
- Documentation that the member has not responded adequately to conservative non-pharmacological therapy (such as physical therapy) for at least 12 weeks; **and**
- Documentation that the member has not adequately responded to, or is unable to tolerate, or has contraindications to at least a 12-week trial of topical or oral non-steroidal anti-inflammatory drugs (NSAIDs); **and**
- **One** of the following:
  - Documentation of treatment failure or inadequate response to at least **two** of the following intra-articular corticosteroid injections for the knee
    - Triamcinolone Acetonide Injection Suspension
    - Methylprednisolone Acetate Injection Suspension
    - Betamethasone Acetate-Betamethasone Sodium Phosphate Injection Suspension
    - Dexamethasone Sodium Phosphate Injection

    or
  - **Both** of the following:
    - History of intolerance, contraindication, or severe adverse event, to at least **two** of the following intra-articular corticosteroid injections for the knee:
      - Triamcinolone Acetonide Injection Suspension
      - Methylprednisolone Acetate Injection Suspension
      - Betamethasone Acetate-Betamethasone Sodium Phosphate Injection Suspension
      - Dexamethasone Sodium Phosphate Injection

      and
    - Physician attests that in their clinical opinion, the same intolerance, contraindication, or severe adverse event would not be expected to occur with Zilretta than experienced with the other products; **and**
- Member is 18 years of age or older; **and**
- Member has not previously been treated with Zilretta; **and**

- Dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; **and**
- Authorization is for no more than 30 days

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim

HCPCS Code	Description
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg

Diagnosis Code	Description
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

Background

Osteoarthritis (OA) is one of the most common causes of chronic disability in adults. OA causes joint pain and altered joint function that are associated with particular pathologic changes in the joint tissues. OA is caused by a variety of factors, including biomechanical factors, proinflammatory mediators, and proteases. The disease may involve synovial joint tissues, including articular cartilage, subchondral bone, ligaments, menisci, periarticular muscles, peripheral nerves, or synovium. This ultimately results in the breakdown of cartilage and bone, leading to symptoms of pain, stiffness, and functional disability. Abnormal intra-articular stress and failure of repair may arise as a result of biomechanical, biochemical, and/or genetic factors. This process may be localized to a single joint, a few joints, or generalized, and the factors that initiate OA likely vary depending on the joint site. There of multiple risk factors consistently associated with knee OA: obesity; previous knee trauma; female gender; older age; and genetic disposition.[4,5,6]

Pain, stiffness, and limitation of motion are the hallmark traits of osteoarthritis. Swelling and joint stability issues may also be present. The location of the pain may help to indicate the site of joint issues. In osteoarthritis of the knee, effusion becomes more common depending on severity.[7,8]

Probable diagnosis can be made without the need for radiological confirmation if the patient meets the following: persistent join pain that is worse with use; 45 years of age or older; morning stiffness that lasts 30 minutes. Other symptoms that can add to the certainty of diagnosis include inactivity pain and crepitus. Radiological evidence (bone thickening, cysts, osteophyte formation) and lack of laboratory inflammation markers also would contribute to confirmation of diagnosis.[9]

Clinical Evidence

Reference the Clinical Studies information provided in the product labeling.[1]

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Zilretta® is an extended-release synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.[1]

References

1. Zilretta® [prescribing information]. San Diego, CA. Pacira BioSciences, Inc.; March 2022.
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3. Devesa L, Bennell K. Management of knee osteoarthritis. UpToDate. Accessed on October 1, 2024.
4. Lane NE, et al. OARSI-FDA initiative: defining the disease state of osteoarthritis. Osteoarthritis Cartilage. 2011;19(5):478-482.
5. Blagojevic M, Jinks C, Jeffery A, Jordan KP. Risk factors for onset of osteoarthritis of the knee in older adults: a systematic review and meta-analysis. Osteoarthritis Cartilage. 2010;18(1):24-33.
6. Kannu P, et al. Premature arthritis is a distinct type II collagen phenotype. Arthritis Rheumatology. 2010;62(5):1421-1430.
7. Hurley MV, et al. Sensorimotor changes and functional performance in patients with knee osteoarthritis. Annals of Rheumatic Disease. 1997;56(11):641-648.
8. Cibere J, et al. Association of clinical findings with pre-radiographic and radiographic knee osteoarthritis in a population-based study. Arthritis Care and Research. 2010;62(12):1691-1698.
9. National Collaborating Centre for Chronic Conditions (UK). Osteoarthritis: National Clinical Guideline for Care and Management in Adults. London: Royal College of Physicians (UK); 2008. NICE Clinical Guidelines, No. 59.
10. Loeser R. Pathogenesis of osteoarthritis. UpToDate. Accessed on September 30, 2022.
11. Deveza L. Management of moderate to severe knee osteoarthritis. UpToDate. Accessed on October 1, 2024.

Policy History/Revision Information

Date	Summary of Changes
12/01/2024	**Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version CSKYD0229.04

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Benefit Drug Policies. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.