MEDICAL MUTUAL®

Drug Policy

Policy:	**201734**	**Initial Effective Date: 12/27/2017**
Code(s):	**HCPCS J3304**	**Annual Review Date: 10/16/2025**
SUBJECT:	**Zilretta™ (triamcinolone acetonide extended-release injectable suspension)**	**Last Revised Date: 10/16/2025**

Subject to: ☐Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

POLICY STATEMENT

This policy involves the use of Zilretta. Prior authorization is recommended for medical benefit coverage of Zilretta. Coverage is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy, and Labs/Diagnostics** for the diagnosis provided. The requirement that the patient meet the Criteria for coverage of the requested medication applies to the initial authorization only. **Waste Management** applies for all covered conditions. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zilretta is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Osteoarthritis pain of the knee.

Criteria. *The patient must meet the following criteria (A, B, C, D, and E):*

A. Patient is 18 year of age or older; AND

B. Patient had an inadequate response, or has a contraindication, or intolerance to triamcinolone injection AND

C. Diagnosis of the knee to be treated is confirmed by radiologic evidence of knee OA (e.g., x-ray, magnetic resonance imaging [MRI], computed tomography [CT] scan, ultrasound); AND

D. The patient has tried at least TWO of the following three modalities of therapy for OA (i or ii; and iii):
   i. At least one course of physical therapy (PT) for knee osteoarthritis; OR
   ii. At least TWO of the following pharmacologic therapies: **[verification of therapies required]**:
      1. NSAIDs (oral [e.g., naproxen, ibuprofen] or topical [Pennsaid® solution or Voltaren® gel], Celebrex® (celecoxib)) [NOTE: a trial of two or more NSAIDs counts as one pharmacologic therapy],

2. acetaminophen
3. tramadol
4. Duloxetine (Cymbalta, generics); AND

iii. At least TWO injections of IA corticosteroids to the affected knee [Note: Triamcinolone injection is a preferred product for commercial and Medicare Part B patients]; AND

E. The product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physical medicine and rehabilitation (physiatrist) or a physician who has received specific training in the administration and use of triamcinolone injections. AND

F. If patient has previously received an injection of Zilretta:
   a. They must have had a beneficial response to the injection; AND
   b. Have had no major safety concerns after receiving the first dose; AND
   c. Must be a minimum of 12 weeks after first dose.

Dosing in OA pain of the knee:

Recommended dosage of 32mg administered as a single intra-articular injection in the knee.

Initial Approval/ Extended Approval.
A) *Initial Approval:*1 injection per knee for 16 weeks.
B) *Extended Approval:* 1 additional injection per knee (16 weeks).

Duration of Therapy in OA knee pain: one-time re-administration per knee.

Labs/Diagnostics. For initial approval, radiologic evidence of osteoarthritis of the affected knee is required as noted in the criteria section.

Waste Management for All Indications.

Zilretta is an injectable suspension that delivers 32 mg of triamcinolone acetonide. It is supplied as a single-dose kit containing one vial of ZILRETTA microsphere powder, one vial of 5 mL diluent, and one sterile vial adapter.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Zilretta 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. Rationale for non-coverage for these specific conditions are provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Zilretta is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids or any component of the product.
2. Zilretta is not suitable for use in small joints, such as the hand.
3. The efficacy and safety of Zilretta for management of osteoarthritis pain of shoulder and hip have not been evaluated.

4. Zilretta has not been evaluated and should not be administered by the following routes: epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes.
5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J3304

REFERENCES

- Zilretta TM (triamcinolone acetonide extended-release injectable suspension) [prescribing information]. Burlington, MA: Flexion Therapeutics, Inc.; May 2024.
- Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee [published correction appears in Arthritis Care Res (Hoboken). 2021 May;73(5):764]. Arthritis Care Res (Hoboken). 2020;72(2):149-162. doi:10.1002/acr.24131Jevsevar D, Brown GA, Jones DL, et al. Treatment of osteoarthritis of the knee, 2nd edition: summary of recommendations. Available at: http://www.aaos.org/research/guidelines/guidelineoaknee.asp. Accessed on May 7, 2015.
- McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis Cartilage. 2014;22(3):363-388
- Paik J, Duggan S, Keam S, Triamciniolone Acetonide Extended-Release: A Review in Osteoarthritis Pain of the Knee. Published online 2019 March, 8. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6437125/ Accessed January, 2020.