Medical Drug Clinical Criteria

Subject:	Zilretta (triamcinolone acetonide extended-release)		
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Overview

This document addresses the use of Zilretta (triamcinolone acetonide extended-release) injection. Zilretta is FDA indicated as an intraarticular injection for the management of osteoarthritis pain of the knee. The efficacy and safety of Zilretta for management of osteoarthritis pain of shoulder and hip have not been evaluated. In addition, Zilretta is not suitable for use in small joints, such as the hand.

Zilretta is administered as a single intra-articular extended-release injection of triamcinolone acetonide, to deliver 32 mg (5 mL) in one dose. Zilretta has not been evaluated and should not be administered by any of the following routes: epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous.

The FDA package label states the efficacy and safety in the repeat administration for the management of osteoarthritis pain of the knee has not been demonstrated. Follow up studies focusing on Zilretta efficacy duration and need for repeat dosing are undergoing.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Zilretta (triamcinolone acetonide extended-release)

Requests for Zilretta (triamcinolone acetonide extended-release) may be approved if the following criteria are met:

I. Individual has a diagnosis of osteoarthritis of the knee; **AND**
II. Individual has not received previous administration of Zilretta to the requested knee; **AND**
III. Requested dose does not exceed 32 mg as a single once in a lifetime intra-articular injection to one knee; **AND**
IV. Individual has not received therapy with an intra-articular short-acting corticosteroid type drugs within the previous 3 months; **AND**
V. Individual has had a therapeutic failure, a contraindication, or is intolerant to all of the following (ACR 2017):
   A. Non-pharmacological therapy, e.g. physical therapy; **AND**
   B. Oral nonsteroidal anti-inflammatory drug (NSAID) at continuous therapeutic dosing (prescription strength); OR topical NSAID if unable to take oral NSAIDs; **AND**
   C. Two (different chemical ingredients per trial) conventional injectable corticosteroids [e.g. Dexamethasone injection, methylprednisolone acetate injection, Kenalog injection (triamcinolone acetonide)].

Requests for Zilretta may not be approved for the following:

I. Individual is using for management of osteoarthritis pain of the shoulder, hip, or small joints, such as the hand; **OR**
II. Individual is requesting a repeat administration in the same knee previously treated with Zilretta for the management of osteoarthritis pain of the knee; **OR**
III. All other indications not included above; **OR**
IV. When the above criteria are not met and for all other indications.

Approval duration: 1 injection per knee per lifetime.

Quantity Limits

Zilretta (triamcinolone acetonide extended-release) Quantity Limits

Drug	Limit
Zilretta 32mg (5 mL) injection	One injection (32 mg/5 mL) per knee per lifetime

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

M17.0-M17.5	Bilateral primary osteoarthritis of the knee

Document History

Revised: 12/11/2023
Document History:

- 12/11/2023 – Annual Review: Updated ACR reference. Coding Reviewed: No changes.
- 06/12/2023 – Select Review: Clarifying use of different chemical ingredients per trial within step therapy. Coding Reviewed: No changes.
- 12/12/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/25/2022 – Annual Review: Wording and formatting changes for document consistency. Coding Reviewed: No changes.
- 3/15/2021 – Select Review: Update Zilretta PA to clarify dosage and administration is allowed in each knee once per lifetime, no repeat administration allowed. Coding Reviewed: Kept M17.0- M17.5 range.
- 12/14/2020 – Annual Review: Updated overview section. No changes to clinical criteria. Coding Reviewed: No changes.
- 08/21/2020 – Annual Review: Add new clinical criteria document for Zilretta Prior Authorization, Step Therapy, and Quantity Limit. Coding Reviewed: Added HCPCS: J3304, ICD-10-CM M17.0-M17.5

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. Barrett J, Coleman B, Arendt E. Practical Tips in the Treatment Of Osteoarthritis of the Knee. Pract Pain Manag. 2012;12(5).
5. Conaghan PG, Hunter DJ, Cohen SB, et al. Effects of a Single Intra-Articular Injection of a Microsphere Formulation of Triamcinolone Acetonide on Knee Osteoarthritis Pain: A Double-Blinded, Randomized, Placebo-Controlled, Multinational Study. *The Journal of Bone and Joint Surgery American*. 2018;100(8):666-677.
6. 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. *Arthritis Care & Research*. 2020; 72 (2):149-162.
7. Zilretta [package insert]. Burlington, MA; Flexion Therapeutics, Incl; Jan 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.