



Zilretta™ (triamcinolone acetonide extended release injection)

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Definitions:

Zilretta (triamcinolone acetonide extended-release injection) is an extended-release synthetic corticosteroid indicated as an intraarticular injection for the management of osteoarthritis pain of the knee. It is not intended for repeat administration or for patients who are allergic to corticosteroids, triamcinolone acetonide, or any other component of the product.

Dosing:

Max Units (per dose and over time):

- 35 billable units per knee per lifetime

Guideline:

Zilretta (triamcinolone acetonide extended-release injection) is considered medically when the following criteria are met:

- Diagnosis of osteoarthritis of the knee; **AND**
- Prescribed by or in consultation with a rheumatologist or an orthopedist; **AND**
- Patient is 18 years of age or older; **AND**
- Failure of ≥ 2 week trial of one of the following (a or b), unless contraindicated or clinically significant adverse effects are experienced:
 - Oral nonsteroidal anti-inflammatory drug (NSAID) at continuous therapeutic dosing (prescription strength); **OR**

- Topical NSAID if member is ≥ 75 years old or unable to take an oral NSAID; **AND**
- History of a positive, but inadequate, response to at least one other intraarticular glucocorticoid injection (i.e. intra-articular immediate-release triamcinolone) for the knee defined as:
 - inadequate pain relief; **OR**
 - frequent need of rescue medications such as NSAIDs or opioids; **OR**
 - need to decrease or inability to increase activity levels; **OR**
 - adequate pain relief accompanied by steroid-induced hyperglycemia.

Limitations/Exclusions

- Approval will be granted for a maximum of 1 dose of Zilretta (triamcinolone acetonide extended-release injection) per knee per lifetime
- Patients who are allergic to corticosteroids, triamcinolone acetonide, or any other component of the product.
- Coverage cannot be renewed

Revisions

12/30/2020	Annual review: no policy changes.
10/31/2019	-Under Guideline, added history of a positive, but inadequate, response to at least one other intraarticular glucocorticoid injection (i.e. intra-articular immediate-release triamcinolone) -Under Limitations/Exclusions, added patients who are allergic to corticosteroids, triamcinolone acetonide, or any other component of the product - updated the Zilretta link in the reference https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208845s000lbl.pdf .
12/3/2018	Added J3304 and removed Q9993 from Applicable Procedure Codes.

Applicable Procedure Codes

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

M17.0	Bilateral primary osteoarthritis of knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of 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

Reference:

- 1) Zilretta Prescribing Information. Burlington, MA: Flexion Therapeutics, Inc.; January 2020.
- 2) Krause VB, Conaghan PG, Aazami HA, et al. Synovial and systemic pharmacokinetics (PK) of triamcinolone acetonide (TA) following intra-articular (IA) injection of an extended release microsphere-based

formulation (FX006) or standard crystalline suspension in patients with knee osteoarthritis (OA).
Osteoarthritis and Cartilage. 2018; 26: 34-42.

- 3) Micromedex database. Available at <http://www.micromedexsolutions.com>. Accessed December 2020.