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 the management of osteoarthritis pain of the shoulder and hip has 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. The FDA package label states Zilretta is not intended for repeat administration for the management of osteoarthritis pain of the knee as the efficacy and safety has not been evaluated. 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. Individual has not received therapy with an intra-articular short-acting corticosteroid type drugs within the previous 3 months; AND
IV. 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 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 repeat administration for the management of osteoarthritis pain of the knee; OR
III. All other indications not included above.

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	Osteoarthritis of knee

Document History

New: 08/21/2020
Document History:

- **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

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4. Triamcinolone Acetonide on Knee Osteoarthritis Pain: A Double-Blinded, Randomized, Placebo- Controlled, Multinational
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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.