



Drug Coverage Policy

Effective Date 8/15/2024

Coverage Policy NumberIP0140

Policy Title.....Zilretta

Corticosteroids (Intraarticular) – Zilretta

- Zilretta® (triamcinolone acetonide extended-release intraarticular injection – Pacira)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

Zilretta, an **extended-release** synthetic corticosteroid, is indicated as an intraarticular injection for the management of **osteoarthritis pain of the knee**.¹

Several other injectable corticosteroids (e.g., betamethasone sodium phosphate and betamethasone acetate, dexamethasone sodium phosphate, methylprednisolone acetate, and immediate-release triamcinolone acetonide) are indicated for intraarticular use for the management of osteoarthritic conditions.²⁻⁵

Dosing Information

Zilretta is administered as a single intraarticular injection that delivers 32 mg/5 mL.¹ Limitation of Use: The efficacy and safety of Zilretta for **repeat** administration have not been demonstrated.

Guidelines

Guidelines for the medical management of osteoarthritis of the hand, hip, and knee are available from the American College of Rheumatology (2019).⁶ Multiple non-pharmacological modalities are recommended for knee osteoarthritis, including exercise, self-management programs, weight loss, Tai Chi, and use of assistive devices (i.e., bracing or a cane). Pharmacologic therapy for knee osteoarthritis consists of acetaminophen, oral and topical non-steroidal anti-inflammatory drugs, tramadol, intraarticular corticosteroid injections, duloxetine, and topical capsaicin. In the guidelines, no distinction is made between the available intraarticular corticosteroid products or between short-acting and long-acting products.

The American Academy of Orthopaedic Surgeons practice guideline for the management of osteoarthritis of the knee (2021) states intraarticular corticosteroids could provide **short-term** relief for patients with symptomatic osteoarthritis of the knee.⁷ Additionally, extended-release intraarticular corticosteroids can be used over immediate-release to improve patient outcomes.

Medical Necessity Criteria

Zilretta is medically necessary when the following are met:

FDA-Approved Indication

- 1. Osteoarthritis Pain of the Knee.** Approve for one injection per treated knee if the patient meets ALL of the following (A, B, and C):
 - A.** Diagnosis of the knee to be treated is confirmed by radiologic evidence of knee osteoarthritis;
AND
Note: Examples of radiologic evidence include diagnosis based on x-ray, magnetic resonance imaging, computed tomography scan, and ultrasound.
 - B.** Patient has tried at least ONE intraarticular corticosteroid injection in the knee to be treated.
Note: Examples of intraarticular corticosteroid injections include immediate-release triamcinolone acetonide, betamethasone sodium phosphate/betamethasone acetate, dexamethasone sodium phosphate, and methylprednisolone acetate.
 - C)** Patient is not receiving re-treatment of knee(s) previously treated with Zilretta.

Dosing. Approve one injection (32 mg/5 mL) administered by intraarticular injection per treated knee.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

Coding Information

- 1) This list of codes may not be all-inclusive.

- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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

References

1. Zilretta® intraarticular injection [prescribing information]. San Diego, CA: Pacira Pharmaceuticals; March 2022.
2. Betamethasone sodium phosphate/betamethasone acetate injection [prescribing information]. Shirley, NY: American Regent; August 2019.
3. Dexamethasone sodium phosphate injection [prescribing information]. Lehi, UT: Civica; November 2019.
4. Methylprednisolone acetate injection [prescribing information]. Bridgewater, NJ: Amneal; November 2020.
5. Immediate-release triamcinolone acetonide injection [prescribing information]. Bridgewater, NJ: Amneal; December 2020.
6. Kolasinski SH, 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 Res.* 2019;72(2):149-162.
7. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. Published August 30, 2021. Available at: <https://www.aaos.org/oak3cpq>. Accessed on May 3, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<p>Osteoarthritis Pain of the Knee. Updated requirement of intraarticular corticosteroid injection from failure, contraindication, or intolerance to tried. Updated 'Patient is not receiving re-treatment of knee(s) previously treated with Zilretta from conditions not covered section to authorization criteria.</p> <p>Conditions Not Covered. Removed 'Treatment in joints other than the knee'</p>	8/15/2024

The policy effective date is in force until updated or retired.

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