Drug Coverage Policy

Effective Date 6/15/2026
Coverage Policy Number.....IP0140
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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

OVERVIEW

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

Limitation of Use: The efficacy and safety of Zilretta for repeat administration have not been demonstrated.

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 in the knee that delivers 32 mg/5 mL.[1]

Guidelines
Guidelines for the 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 (nonarthroplasty) [2022] state 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 (moderate strength recommendation).

Coverage Policy

Policy Statement
Prior Authorization is required for benefit coverage of Zilretta. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zilretta as well as the monitoring required for adverse events and long-term efficacy, approval requires Zilretta to be prescribed by a physician who has consulted with or who specializes in the condition.

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

Zilretta for any other use is considered not medically necessary. Criteria will be updated as newly published data are available.

Coding Information

Note: 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; April 2026.
2. Betamethasone sodium phosphate/betamethasone acetate injection [prescribing information]. Shirley, NY: American Regent; June 2020.
3. Dexamethasone sodium phosphate injection [prescribing information]. Lehi, UT: Civica; November 2019.
4. Methylprednisolone acetate injection [prescribing information]. Bridgewater, NJ: Amneal; July 2021.
5. 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. Brophy RH, Fillingham YA. AAOS Clinical Practice Guideline Summary: Management of Osteoarthritis of the Knee (Nonarthroplasty), Third Edition. *J Am Acad Orthop Surg*. 2022;30(9):e721-e729.

Revision Details

Summary of Changes	Review Date	Effective Date
Osteoarthritis Pain of the Knee. **Updated** requirement of intraarticular corticosteroid injection from failure, contraindication, or intolerance to tried.	5/30/2024	8/15/2024

Updated 'Patient is not receiving re-treatment of knee(s) previously treated with Zilretta from conditions not covered section to authorization criteria. **Conditions Not Covered.** **Removed** 'Treatment in joints other than the knee'		
No criteria changes.	5/22/2025	8/1/2025
No criteria changes	5/21/2026	6/15/2026

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

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2026 The Cigna Group.