

Zilretta® (triamcinolone acetonide ER) (Intra-articular)

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I. Length of Authorization ¹

Coverage will be provided for one dose per knee and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Zilretta 32 mg single-dose vial: 1 vial per knee

B. Max Units (per dose and over time) [HCPCS Unit]:*

- 64 billable units one time only*

*Max units are based on administration to both knees

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patients must have a contraindication or intolerance to a short-acting corticosteroid (i.e., triamcinolone acetonide injectable suspension [Kenalog™]) prior to consideration of Zilretta; **AND**

- Patient is at least 18 years of age; **AND**

Universal Criteria ^{1,8,13}

- Patient does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, etc.); **AND**
- Patient has not received therapy with intra-articular hyaluronic acid derivative drugs within the previous 6 months of therapy; **AND**
- Patient has not received therapy with intra-articular short-acting corticosteroid type drugs within the previous 3 months of therapy; **AND**

Osteoarthritis of the knee † ^{1,8,12-14}

- Patient has a radiographically* confirmed diagnosis of osteoarthritis of the knee; **AND**
- The patient has had a trial and failure to BOTH of the following conservative methods which have not resulted in functional improvement after at least three (3) months:
 - Non-Pharmacologic (i.e., physical, psychosocial, or mind-body approach [e.g., exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.]); **AND**
 - Pharmacologic Approach (e.g., topical NSAIDs, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.); **AND**
- The patient has failed to adequately respond to, or has a contraindication to, aspiration and injection of a short-acting intra-articular corticosteroid; **AND**
- The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)

**Note: Imaging is not required to make the diagnosis in patients with a typical presentation of OA¹¹*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration (per knee) ¹

Indication	Dose
Osteoarthritis of the knee	Administer 32 mg as a single intra-articular injection to the affected knee(s).

VI. Billing Code/Availability Information

HCPCS Code:

- J3304 – Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg; 1 billable unit = 1 mg

NDC:

- Zilretta single-dose kit (containing 32 mg triamcinolone acetonide extended-release injectable powder for suspension with 5 mL of sterile diluent): 65250-0003-xx

VII. References

1. Zilretta [package insert]. San Diego, CA; Pacira Pharmaceuticals, Inc.; March 2022. Accessed August 2023.

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6. Brown GA. AAOS clinical practice guideline: treatment of osteoarthritis of the knee: evidence-based guideline, 2nd edition. *J Am Acad Orthop Surg*. 2013 Sep;21(9):577-9. doi: 10.5435/JAAOS-21-09-577.
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11. Sakellariou G, Conaghan PG, Zhang W, et al. EULAR recommendations for the use of imaging in the clinical management of peripheral joint osteoarthritis. *Annals of the Rheumatic Diseases* 2017;76:1484-1494.
12. National Institute for Health and Care Excellence. NICE 2022. Osteoarthritis in over 16s: diagnosis and management. Published Oct 2022. Clinical guideline NG226. <https://www.nice.org.uk/guidance/ng226>. Accessed August 2023.

13. Brophy RH, Fillingham YA. AAOS Clinical Practice Guideline Summary: Management of Osteoarthritis of the Knee (Nonarthroplasty), Third Edition. J Am Acad Orthop Surg. 2022 May 1;30(9):e721-e729. doi: 10.5435/JAAOS-D-21-01233.
14. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (NonArthroplasty) Evidence-Based Clinical Practice Guideline. <https://www.aaos.org/oak3cpg> Published August 30, 2021.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified 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
M17.9	Osteoarthritis of knee, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC