

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

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I. Length of Authorization

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]:*

- 32 billable units one time only*

*Max units are based on administration to a single knee

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}

- 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}

- 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 has not resulted in functional improvement after at least three (3) months: ^{9,10}
 - 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 with 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) ^{1,8}

† FDA Approved Indication(s)

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration (per knee) ¹

Indication	Dose
OA pain 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): 70801-0003-xx

VII. References

1. Zilretta [package insert]. Burlington, MA; Flexion Therapeutics, Incl; January 2020. Accessed September 2020.
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3. Russell SJ, Sala R, Conaghan PG, et al. Triamcinolone acetonide extended-release in patients with osteoarthritis and Type 2 diabetes: a randomized, phase 2 study. *Rheumatology*. 2018
4. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res (Hoboken)*. 2012 Apr;64(4):465-74.
5. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014 Mar;22(3):363-88. doi: 10.1016/j.joca.2014.01.003. Epub 2014 Jan 24.
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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8. American College of Rheumatology. Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC). *Rheumatology.org*. <https://www.rheumatology.org/i-am-a-rheumatologist/research/clinician-researchers/western-ontario-mcmaster-universities-osteoarthritis-index-womac>. Published 2015.
9. Kolasinski SL, 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 Rheumatol*. 2020 Feb;72(2):220-233. doi: 10.1002/art.41142. Epub 2020 Jan 6.
10. Bannuru RR, Osani MC, Vaysbrot EE, et al OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage*. 2019 Nov;27(11):1578-1589. doi: 10.1016/j.joca.2019.06.011. Epub 2019 Jul 3.

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
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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: <http://www.cms.gov/medicare-coverage-database/search/advanced-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.
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