Medical Policy:

Zilretta (triamcinolone acetonide extended release) Intra-articular

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.59	January 2, 2025	November 29, 2018

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Zilretta (triamcinolone acetonide extended-release injectable suspension) is an extended-release synthetic corticosteroid is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.

Length of Authorization

Limitations/Exclusions

1. Approval will be granted for a maximum of 1 dose of Zilretta (triamcinolone acetonide extended-release injection) per knee
2. Patients who are allergic to corticosteroids, triamcinolone acetonide, or any other component of the product.
3. Coverage cannot be renewed

Limitation of Use

The efficacy and safety of repeat administration of Zilretta have not been demonstrated.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 32 billable units per knee per lifetime

Guideline

Zilretta (triamcinolone acetonide extended-release injection) is considered medically when the following criteria are met:

1. Diagnosis of osteoarthritis of the knee; **AND**
2. Prescribed by or in consultation with a rheumatologist or an orthopedist; **AND**
3. Patient is 18 years of age or older; **AND**
4. Failure of ≥ 3 month trial of one of the following (a or b AND c), unless contraindicated or clinically significant adverse effects are experienced:
    a. Oral nonsteroidal anti-inflammatory drug (NSAID) at continuous therapeutic dosing (prescription strength); **OR**
    b. Topical NSAID if member is ≥ 75 years old or unable to take an oral NSAID; **AND**
    c. 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**
5. History of a positive, but inadequate, response to at least one other intraarticular glucocorticoid injection (i.e. intra-articular immediate-release triamcinolone) for the knee defined as:
    a. inadequate pain relief; **OR**
    b. frequent need of rescue medications such as NSAIDs or opioids; **OR**
    c. need to decrease or inability to increase activity levels; **OR**
    d. adequate pain relief accompanied by steroid-induced hyperglycemia; **AND**
6. The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)

Applicable Procedure Codes

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

ICD-10 Diagnoses

Code	Description
M17.0	Bilateral primary osteoarthritis of knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of 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

Revision History

Company(ies)	DATE	REVISION

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EmblemHealth & ConnectiCare	1/2/2025	Annual Review: Initial Criteria: Removed “2 week” in the following statement and replaced with “3 month” : “Failure of ≥ 3 month trial of one of the following (a or b AND c), unless contraindicated or clinically significant adverse effects are experienced:“ Added: “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” added: “The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)”
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/6/2023	Annual Review: no revisions
EmblemHealth & ConnectiCare	5/25/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	5/23/2022	-Updated Limitations/Exclusions section: Removal of “per lifetime” from- Approval will be granted for a maximum of 1 dose of Zilretta (triamcinolone acetonide extended-release injection) per knee.
EmblemHealth & ConnectiCare	2/14/2022	-Updated Definitions section removing language stating that Zilretta was "not intended for repeat administration." Added limitation of use per label that states "efficacy and safety of repeat administration of Zilretta have not been demonstrated" -Under billable units: changed from 35 to 32 billable units -Removal of 2017 Package insert link in references. Replaced with current link: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208845s007lbl.pdf
EmblemHealth & ConnectiCare	12/30/2020	Annual review: no policy changes.
EmblemHealth & ConnectiCare	10/31/2019	-Under Guideline, added history of a positive, but inadequate, response to at least one other intraarticular glucocorticoid injection (i.e. intra-articular immediate-release triamcinolone) -Under Limitations/Exclusions, added patients who are allergic to corticosteroids, triamcinolone acetonide, or any other component of the product
EmblemHealth & ConnectiCare	12/3/2018	Added J3304 and removed Q9993 from Applicable Procedure Codes.

References

1. Zilretta Prescribing Information. Burlington, MA: Flexion Therapeutics, Inc.; January 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208845s007lbl.pdf
2. Krause VB, Conaghan PG, Aazami HA, et al. Synovial and systemic pharmacokinetics (PK) of triamcinolone acetonide (TA) following intra-articular (IA) injection of an extended release microsphere-based formulation (FX006) or standard crystalline suspension in patients with knee osteoarthritis (OA). Osteoarthritis and Cartilage. 2018; 26: 34-42.
3. Micromedex database. Available at http://www.micromedexsolutions.com. Accessed December 2020.

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