Medical Policy

Zilretta™ (triamcinolone acetonide extended release injection)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_095
CURRENT VERSION EFFECTIVE DATE	1/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Zilretta™ (triamcinolone acetonide extended release injection) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Zilretta will be provided for a maximum of 1 dose of Zilretta (triamcinolone acetonide
extended-release injection) per knee per lifetime.
Dosing Limitation: 35 billable units per knee per lifetime

A. Patient is 18 years of age or older; **AND**
B. Zilretta is prescribed by, or in consultation with, a rheumatologist or an orthopedist; **AND**
C. Patient has a clinical diagnosis of osteoarthritis of the knee; **AND**
D. Patient has had a trial and failure of at least a 2 week trial of **one** of the following (a or b), 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 patient is 75 years of age or older or unable to take an oral NSAID; **AND**
E. 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.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Patients who are hypersensitive to triamcinolone acetonide or other corticosteroids.

BACKGROUND

Zilretta (triamcinolone acetonide extended-release injection) is an extended-release synthetic corticosteroid indicated as an intraarticular injection for the management of osteoarthritis pain of the knee. It is not intended for repeat administration or for patients who are allergic to corticosteroids, triamcinolone acetonide, or any other component of the product.

DEFINITIONS

1. ZILRETTA (triamcinolone acetonide extended-release injectable suspension), for intraarticular us
    a. ZILRETTA (triamcinolone acetonide extendedrelease injectable suspension) single-dose kit

CODING

Applicable NDC Codes	
70801-0003-01	ZILRETTA (triamcinolone acetonide) 32 mg vial

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

Applicable ICD-10 Codes	
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

EVIDENCE BASED REFERENCES

1. Product Information: ZILRETTA(R) extended-release intra-articular injectable suspension, triamcinolone acetonide extended-release intra-articular injectable suspension. Flexion Therapeutics Inc (per manufacturer), Burlington, MA, 2020.

POLICY HISTORY

Original Effective Date	1/1/2022
Revised Date	November 8, 2022 – Annual Review and approval (no policy revisions made) March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	11/8/2022

Approved by Pharmacy and Therapeutics Committee on 11/8/2022