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5.70.065

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	October 27, 2017
Subject:	Zilretta	**Page:**	1 of 5

Last Review Date: September 6, 2024

Zilretta

Description

Zilretta (triamcinolone injectable suspension)

Background
Osteoarthritis is a degenerative joint disease characterized by cartilage degradation, bone remodeling, osteophyte formation, and synovial inflammation, leading to pain, stiffness, swelling, and loss of normal joint function. The 2019 American College of Rheumatology (ACR) Osteoarthritis Guideline outlines a comprehensive plan for the management of osteoarthritis including educational, behavioral, psychosocial, and physician interventions, as well as topical, oral, and intraarticular medications. Zilretta (triamcinolone injectable suspension) is an intra-articular corticosteroid injection indicated to manage osteoarthritis knee pain (1-2).

Regulatory Status
FDA-approved indication: Zilretta is an extended-release synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain of the knee (2).

Limitations of Use:
The efficacy and safety of repeat administration of Zilretta have not been demonstrated (2).

The efficacy and safety of Zilretta for management of osteoarthritis pain of shoulder and hip have not been evaluated (2).

Zilretta has warnings regarding intra-articular use only, serious neurologic adverse reactions with epidural and intrathecal administration, hypersensitivity reactions and joint infection and

damage. This product is only intended for intra-articular use. Do not administer Zilretta by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. Serious neurologic events have been reported following epidural or intrathecal corticosteroid administration. Corticosteroids are not approved for this use. Serious reactions have been reported with triamcinolone acetonide injection. Institute appropriate care upon occurrence of an anaphylactic reaction. This medication may cause joint pain accompanied by joint swelling. If this occurs, conduct appropriate evaluation to exclude septic arthritis and institute appropriate antimicrobial therapy if septic arthritis is confirmed (2).

Safety and effectiveness in pediatric patients have not been established (2).

Related policies
Hyaluronic Acid Derivatives

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zilretta may be considered **medically necessary** if the conditions indicated below are met.

Zilretta may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Osteoarthritis of the knee(s)

AND ALL of the following:

1. Inadequate response to **TWO** or more of the following conservative non-pharmacologic therapy:
    a. Cardiovascular (aerobic) activity, such as: walking, biking, stationary bike, aquatic exercise

b. Resistance exercise
c. Weight reduction (for persons who are overweight)
d. Participation in self-management programs
e. Wear of medially directed patellar taping
f. Wear of wedged insoles
g. Thermal agents
h. Walking aids
i. Physical therapy
j. Occupational therapy

2. Inadequate response, intolerance, or contraindication to **TWO** or more of the following:
    a. Acetaminophen
    b. Oral NSAIDs
    c. Topical NSAIDs

3. Inadequate response, intolerance, or contraindication to **SHORT** acting intra-articular steroid injections in which efficacy lasted less than 8 weeks

4. Radiologic confirmation of Kellgren-Lawrence Scale score of grade 2 or greater

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 1 injection per knee per lifetime

Prior – Approval *Renewal* Limits

None

Rationale

Summary
Osteoarthritis is a degenerative joint disease characterized by cartilage degradation, bone remodeling, osteophyte formation, and synovial inflammation, leading to pain, stiffness, swelling, and loss of normal joint function. Zilretta (triamcinolone injectable suspension) is an extended-release synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain of the knee. The efficacy and safety of repeat administration of Zilretta have not been demonstrated (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zilretta while maintaining optimal therapeutic outcomes.

References

1. 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 Care Res (Hoboken)*. 2020;72(2):149-162. doi:10.1002/acr.24131.
2. Zilretta [package insert]. San Diego, CA: Pacira Therapeutics, Inc.; May 2024.

Policy History

Date	Action
October 2017	Addition to PA
March 2018	Annual editorial review Removal of Tramadol from the T/F list per SME
June 2018	Annual review
March 2019	Annual review and reference update
March 2020	Annual review and reference update
May 2021	Updated limitations of use to align with the package insert
September 2021	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.70.065
September 2023	Annual review
June 2024	Annual review
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.