

<b>Department:</b>	Pharmacy	<b>Original Approval:</b>	01/10/2019
<b>Policy #:</b>	PM569	<b>Last Approval:</b>	01/10/2019
<b>Title:</b>	Triamcinolone ER (Zilretta)		
<b>Approved By:</b>	UM Pharmacy Subcommittee		

## REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Triamcinolone extended-release injection: History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Medication list (current and past) -Current and past treatment modalities, including physical therapy -Product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physiatrist -Dosing and duration of therapy -Imaging/Radiology.

## BACKGROUND

ZILRETTA is an extended-release synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain of the knee. Triamcinolone acetonide is a corticosteroid with anti-inflammatory and immunomodulating properties. It binds to and activates the glucocorticoid receptor, leading to activation of anti-inflammatory transcription factors such as lipocortins and inhibition of inflammatory transduction pathways by blocking the release of arachidonic acid and preventing the synthesis of prostaglandins and leukotrienes.

### Guidelines

Guidelines for the medical management of OA of the hand, hip, and knee were published in 2012 by the American College of Rheumatology (ACR). Initial pharmacologic therapy for knee OA consists of acetaminophen, oral and topical non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, and corticosteroid injections.

## DEFINITIONS

Enter all definitions here.

## INDICATIONS/CRITERIA

<b>Medicaid Members</b>	<i>Continue to criteria for approval below.</i>
<b>Medicare Members</b>	<i>Step-utilization of Part D drugs not required.</i>

Coverage of Triamcinolone acetonide extended-release injection is recommended in those who meet the following criteria:

### **1. Osteoarthritis of the Knee**

Criteria. *Patient must meet the following criteria (A, B, C, D, and E):*

- A. Prescribed by a rheumatologist, orthopedic specialist, or physiatrist AND
- B. Patient is 18 years of age or older AND
- C. Diagnosis of the knee to be treated is confirmed by radiologic evidence of knee OA (e.g., x-ray, magnetic resonance imaging [MRI], computed tomography [CT] scan, ultrasound); AND
- D. Medical record documentation that patient has not received a previous administration of Zilretta to the requested knee AND
- E. The patient has tried at least TWO of the following three modalities of therapy for OA (i, ii, iii):
  - i. At least one course of physical therapy (PT) for knee osteoarthritis; OR
  - ii. At least TWO of the following pharmacologic therapies (a, b, c, or d) **[verification of therapies required]**:
    - a) Nonsteroidal anti-inflammatory drug (NSAID), oral or topical (examples of oral agents include naproxen, ibuprofen, Celebrex® [celecoxib capsules]; examples of topical NSAIDs include: diclofenac solution [e.g., Pennsaid®] or diclofenac 1% gel [e.g., Voltaren® gel]) [NOTE: a trial of two or more NSAIDs {oral and/or topical} counts as one pharmacologic therapy];
    - b) Acetaminophen;
    - c) Tramadol (Ultram®/XR, generics);
    - d) Duloxetine (Cymbalta®, generics);
  - iii. At least TWO injections of IA corticosteroids to the affected knee

### **Dosing**

Recommended dosage of 32mg administered as a single intra-articular injection in the knee.

### **Initial Approval**

- A. One injection per knee

### **Extended Approval**

- B. None. Zilretta is not intended for repeat administration

### **Duration of Therapy**

One-time administration per knee

### **Labs/Diagnostics**

For initial approval, radiologic evidence of osteoarthritis of the affected knee is required as noted in the criteria section.

### **Waste Management**

Zilretta is an injectable suspension that delivers 32mg of triamcinolone acetonide. It is supplied as a single-dose kit containing one vial of Zilretta microsphere powder, one vial of 5mL diluent, and one sterile vial adapter.

**Conditions not recommended for approval**

Osteoarthritis of the shoulder and hip.

**SPECIAL CONSIDERATIONS**

None.

**LIMITATIONS/EXCLUSIONS**

Please refer to a product line’s certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	<a href="http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides">http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides</a>
WASHINGTON APPLE HEALTH	<a href="http://chpw.org/our-plans/apple-health/">http://chpw.org/our-plans/apple-health/</a>
INTEGRATED MANAGED CARE	<a href="http://chpw.org/our-plans/apple-health/">http://chpw.org/our-plans/apple-health/</a>

**Citations & References**

<b>CFR</b>	
<b>WAC</b>	<a href="#">WAC 284-43-2050</a>
<b>RCW</b>	
<b>Contract Citation</b>	<input checked="" type="checkbox"/> WAH <input checked="" type="checkbox"/> IMC <input checked="" type="checkbox"/> MA
<b>Other Requirements</b>	
<b>NCQA Elements</b>	
<b>References</b>	<ol style="list-style-type: none"> <li>1. Zilretta TM (triamcinolone acetonide extended-release injectable suspension) [prescribing information]. Burlington, MA: Flexion Therapeutics, Inc.; May 2018</li> <li>2. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of</li> </ol>

	<p>nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care Res. 2012;64:465-474.</p> <p>3. Jevsevar D, Brown GA, Jones DL, et al. Treatment of osteoarthritis of the knee, 2<sup>nd</sup> edition: summary of recommendations. Available at:  <a href="http://www.aaos.org/research/guidelines/guidelineoaknee.asp">http://www.aaos.org/research/guidelines/guidelineoaknee.asp</a>. Accessed on Jan 2, 2019.</p> <p>4. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSJ guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis Cartilage. 2014;22(3):363-388.</p>
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### Revision History

Revision Date	Revision Description	Revision Made By
01/02/2019	New policy	Jennifer Farley, PharmD
01/10/2019	Approval	UM Pharmacy Subcommittee