Zilretta (triamcinolone injectable suspension)

Background
Osteoarthritis of the knee is a common problem within the United States, afflicting approximately 240 per 100,000 people. Treatments of osteoarthritis of the knees include the use of self-management programs, strengthening, low-impact aerobic exercise, and neuromuscular education. Pharmacological interventions include NSAIDs (both topically and orally), Tylenol, and opioids for symptomatic pain control. Intra-articular corticosteroid injections have been used frequently to help with pain and to decrease swelling. Zilretta is an intra-articular corticosteroid that has been formulated for extended release, which is intended to increase the time of effect of the corticosteroid (1-3).

Regulatory Status
FDA approved indication: Zilretta (triamcinolone acetonide extended-release injectable suspension) is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee (3).

Limitations of Use:
Zilretta is not intended for repeat administration (3).

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 (3).

Safety and effectiveness in pediatric patients have not been established (3).

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 for the treatment of osteoarthritis of the knee(s) in patients 18 years of age or older when the conditions indicated below are met.

Zilretta may be considered investigational in patients less than 18 years of age and 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 of the knee is a very common condition in the United States. Many modalities have been integrated for the treatment of osteoarthritis of the knee including lifestyle changes (exercise, bracing, weight loss, etc.), oral and topical analgesics, as well as intra-articular steroid shots. Zilretta is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee. Zilretta is not intended for repeat administration (1-3).

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

References

Policy History

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<td>October 2017</td>
<td>Addition to PA</td>
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<tr>
<td>March 2018</td>
<td>Annual editorial review</td>
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<td>Removal of Tramadol from the T/F list per SME</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.