

**Policy: MBP 178.0**

**Section: Medical Benefit Pharmaceutical Policy**

**Subject: Zilretta (triamcinolone acetonide ER injection)**

### **I. Policy:**

Zilretta (triamcinolone acetonide ER injection)

### **II. Purpose/Objective:**

To provide a policy of coverage regarding Zilretta (triamcinolone acetonide ER injection)

### **III. Responsibility:**

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

### **IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

### **V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

### **Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

**DESCRIPTION:**

Zilretta (triamcinolone acetonide ER injection) is an extended-release intra-articular injection of triamcinolone that is indicated for the management of osteoarthritis pain of the knee. It is a long acting corticosteroid with minimal sodium-retaining potential. Decreases inflammation by suppression of migration of polymorphonuclear leukocytes and reversal of increased capillary permeability.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

Zilretta (triamcinolone acetonide ER injection) will be considered medically necessary for Commercial, Exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

- Prescribed by a rheumatologist or orthopedic specialist **AND**
- Patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of osteoarthritic pain of the knee **AND**
- Medical record documentation that patient has not received a previous administration of Zilretta to the requested knee **AND**
- Medical record documentation that non-pharmacologic modalities (e.g. Weight loss, aerobic/resistance land-based exercise or aquatic exercise, other physical therapy modalities or exercises) have not promoted satisfactory symptomatic relief **AND**
- Medical record documentation that there has been no significant improvement following a 10-12 week trial of full-dose nonsteroidal anti-inflammatory drug (NSAID) therapy, with or without supplemental acetaminophen **OR** if NSAIDs are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period **AND**
- Medical record documentation of a therapeutic failure on or intolerance to two different intra-articular steroid injections (e.g. triamcinolone, methylprednisolone, betamethasone, dexamethasone).

**AUTHORIZATION DURATION:** One injection per knee per lifetime (Facets RX count 32 per knee per lifetime, Darwin RX count 1)

**NOTES:**

- The safety and efficacy of repeat administrations of Zilretta have not been studied.
- The safety and efficacy of Zilretta for management of osteoarthritis pain in joints other than the knee have not been studied.
- Zilretta is for intra-articular use only and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

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Zilretta (triamcinolone acetonide ER injection) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescribed by a rheumatologist or orthopedic specialist **AND**
- Patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of osteoarthritic pain of the knee **AND**
- Medical record documentation that patient has not received a previous administration of Zilretta to the requested knee **AND**
- Medical record documentation that non-pharmacologic modalities (e.g. Weight loss, aerobic/resistance land-based exercise or aquatic exercise, other physical therapy modalities or exercises) have not promoted satisfactory symptomatic relief **AND**
- Medical record documentation that there has been no significant improvement following a 10-12 week trial of full-dose nonsteroidal anti-inflammatory drug (NSAID) therapy, with or without supplemental acetaminophen **OR** if NSAIDs are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period.

**AUTHORIZATION DURATION:** One injection per knee per lifetime (Facets RX count 32 per knee per lifetime, Darwin RX count 1)

**NOTES:**

- The safety and efficacy of repeat administrations of Zilretta have not been studied.
- The safety and efficacy of Zilretta for management of osteoarthritis pain in joints other than the knee have not been studied.
- Zilretta is for intra-articular use only and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes.

**LINE OF BUSINESS:**

**Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.**

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 5/15/18

**Revised:** 12/17/22 (LOB carve out, Medicaid PARP statement), 12/6/23 (Medicaid business segment)

**Reviewed:** 4/22/19, 1/1/20, 1/1/21, 12/17/21

**MA UM Committee approval:** 12/31/23