



POLICIES AND PROCEDURE MANUAL

Policy: MBP 178.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Zilretta (triamcinolone acetonide ER injection)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

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, 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.

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 **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)

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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.

REFERENCES:

1. Zilretta [prescribing information]. San Diego, CA: Pacira Pharmaceuticals Inc; February 2024.
2. Kolaianaki 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. American College of Rheumatology (ACR). Arthritis & Rheumatology; 2020 February. 72(2):220-233. Available from: <https://rheumatology.org/osteoarthritis-guideline>
3. Management of Osteoarthritis of the Knee (Non-Arthroplasty): Evidence-Based Clinical Practice Guideline. American Academy of Orthopaedic Surgeons (AAOS); 2021 Aug 31 [cited 2023 Dec 26]. Available from: <https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf>

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, references), 11/29/24 (added alts for Medicare, LOB table, taglines, removed Darwin)

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

MA UM Committee approval: 12/31/23