Ziconotide (Prialt®)	Place of Service Hospital Administration Infusion Center Administration Office Administration Outpatient Facility Infusion Administration HCPCS: J2278 per 1 mcg

Condition listed in policy *(see criteria for details)*:

- Management of severe chronic pain

AHFS therapeutic class: Analgesics and Antipyretics, miscellaneous

Mechanism of action: Ziconotide, a synthetic form of a conopeptide isolated from the venom of the marine snail *Conus magus*, is a potent nonopiate analgesic.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Prialt® (ziconotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Management of severe chronic pain

1. Patient is appropriately managed in a comprehensive pain management program, **AND**
2. One of the following:
    a. Inadequate response or intolerance to intrathecal morphine, **OR**
    b. Insufficient clinical response with maximally tolerated doses of systemic non-opioid analgesics, **OR**
    c. Being used to reduce opioid use

Covered Doses
Up to 19.2 mcg/day (0.8 mcg/hr) continuous infusion intrathecally

Coverage Period
Indefinite

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Prialt® (ziconotide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Acute pain
- Severe chronic pain adequately being managed with systemic analgesics, adjunctive therapies, or intrathecal morphine

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:
100 mcg, 500mcg (Intrathecal Solution)

Administration:
Prialt is given intrathecally via an implanted Medtronic SynchroMed® II infusion system or a Smiths Medical CADD-Micro Ambulatory Infusion Pump.

Devices have a battery life of 5-7 years, depending on flow rate of medication. *Prialt is not intended for intravenous or epidural administration.*

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Prialt® (ziconotide) [Prescribing information]. Lake Forest, IL: TerSera Therapeutics. 5/2019.

(7) Policy Update

Date of last review: 1Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee