Medical Drug Clinical Criteria

Subject:	Prialt (ziconotide)		
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Overview

This document addresses the use of Prialt (ziconotide), a non-opioid analgesic for intrathecal administration. Prialt is approved to treat pain in individuals with severe chronic pain where intrathecal therapy is warranted and who are intolerant or refractory to other treatments such as systemic analgesic or intrathecal morphine. Prialt binds to N-type calcium channels in the spinal cord, preventing pain signals from reaching the brain.

Prialt has a black box warning regarding the potential of neuropsychiatric adverse events. Prialt is contraindicated in those with a preexisting history of psychosis. Individuals should be monitored for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. Prialt should be discontinued in the event of serious neurological or psychiatric signs or symptoms.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Prialt (ziconotide)

Requests for Prialt (ziconotide) may be approved if the following criteria are met:

I. Individual has a diagnosis of severe chronic pain; **AND**
II. Intrathecal therapy for chronic pain is warranted; **AND**
III. Individual is intolerant of or refractory to other treatment, including systemic analgesics, adjunctive therapies or intrathecal morphine.

Requests for Prialt (ziconotide) may not be approved for the following:

I. Individual is using to treat other pain types, including but not limited to post-operative pain, acute brain injury, and spasticity associated with spinal cord trauma; **OR**
II. Individual has a pre-existing history of psychosis; **OR**
III. Individual has a contraindication to intrathecal administration of medications, including presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of cerebrospinal fluid (CSF); **OR**
IV. May not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J2278	Injection, ziconotide, 1 microgram [Prialt]

ICD-10 Diagnosis

G89.21-G89.4	Chronic pain syndrome

Document History

Revised: 11/18/2022
Document History:

- 11/18/2022 – Annual Review: Minor wording and formatting changes. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/20/2020 – Annual Review: No changes. Coding Reviewed: Added ICD-10-CM-G89.21-G89.4.
- 11/15/2019 – Annual Review: Minor wording and formatting changes. Coding Reviewed: No changes
- 11/16/2018 – Annual Review: First P&T review of Prialt. Updated may not be approved criteria to include contraindications for use per label. HCPCS and ICD-10 Coding review: no changes.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 10, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.