



**Ziconotide Intrathecal Infusion (PRIALT®)**

**Policy Number: M-0045**

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

**Coverage Guidelines:**

FDA

- Severe and Chronic Pain

Off-Label

- Spasticity
- Spinal Cord Injury

**Coding Information:**

HCPCS Code(s)

J2278	INJECTION, ZICONOTIDE, 1 MICROGRAM
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**Limitations:**

According to the package insert, Prialt® (ziconotide intrathecal infusion) is indicated for the management of severe chronic pain in patients for whom intrathecal (IT) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

Providers are reminded that the documentation in the medical record must show the patient is intolerant of or refractory to the 'other treatment' as noted in the package insert. Providers are reminded that the documentation in the medical record must show the patient is intolerant of or refractory to the 'other treatment' as noted in the package insert.



**Background:**

Ziconotide is a selective, potent, and reversible blocker of N-type voltage-sensitive calcium channels (VSCCs). N-type VSCCs are found at presynaptic nerve terminals in the dorsal horn region of the spinal cord, which is innervated by small myelinated and unmyelinated nociceptive afferents from the dorsal roots. N-type calcium channels are present in highest density in the superficial layers (Rexed laminae I and II) of the dorsal horn, which is the site of primary afferent nociceptive synapses. N-type VSCCs control depolarization-induced neurotransmitter release at the primary afferent nerve terminal. Although the mechanism of action has not been established in humans, ziconotide appears to produce analgesia (modify nociception) by binding to VSCCs and thus, blocking neurotransmitter release from primary nociceptive afferents terminating in the superficial layers of the spinal cord dorsal horn. Also, calcium channels may be involved with maintenance of spontaneous ectopic discharges in injured primary afferent nociceptors and with mediation of persistent tactile allodynia after nerve injury. Thus, ziconotide, by blocking calcium influx through neuronal N-type VSCCs, may influence neuronal excitability modulation. Ziconotide does not bind to opiate receptors, and its pharmacological effects are not blocked by opiate antagonists.

**Definitions:**

**HCPCS Code**—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

**ICD-9 Code**—International Classification of Disease, 9<sup>th</sup> edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.



### FDA Black Box Warning:

#### **WARNING: NEUROPSYCHIATRIC ADVERSE REACTIONS**

**PRIALT is contraindicated in patients with a preexisting history of psychosis. Severe psychiatric symptoms and neurological impairment may occur during treatment with PRIALT. Monitor all patients frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. Discontinue PRIALT therapy in the event of serious neurological or psychiatric signs or symptoms.**

### References:

1. Prialt. In: Clinical Pharmacology. Tampa (FL): Gold Standard. [updated 3/15/10; accessed 11/15/12]. <https://www.clinicalpharmacology.com/Forms/drugoptions.aspx?cpnum=2298&n=Prialt&t=0>.
2. Prialt. In: Micromedex 2.0. Greenwood Village (CO): Thompson Reuters. [updated 08/28/11; accessed 11/15/12]. [http://www.thomsonhc.com/micromedex2/librarian/ND\\_T/evidencexpert/ND\\_PR/evidencexpert/CS/C13771/ND\\_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/2CE635/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_P/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=prialt](http://www.thomsonhc.com/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/C13771/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/2CE635/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=prialt).
3. Prialt [package insert]. Philadelphia, PA: Azur Pharma International Limited: 2010.
4. Local Coverage Article for Drugs and Biologicals - Ziconotide Intrathecal Infusion (Prialt<sup>®</sup>) (J2278) (A51059) (Original). Available at: [http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=51059&ver=5&ContrlId=213&ContrVer=1&CntrctrSelected=213\\*1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Alabama&CptHcpcsCode=J2278&clickon=search&bc=gAAABAAAA&".](http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=51059&ver=5&ContrlId=213&ContrVer=1&CntrctrSelected=213*1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Alabama&CptHcpcsCode=J2278&clickon=search&bc=gAAABAAAA&) Accessed November 16, 2012.
5. Local Coverage Determination (LCD) for External Infusion Pumps (L11555) (Revision 23). Available at: [http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11555&ContrlId=140&ver=72&ContrVer=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Alabama&CptHcpcsCode=J2278&clickon=search&bc=gAAABAAAA&".](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11555&ContrlId=140&ver=72&ContrVer=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Alabama&CptHcpcsCode=J2278&clickon=search&bc=gAAABAAAA&) Accessed November 16, 2012.

### Document History:

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