

PRIALT®

(ZICONOTIDE)
INTRATHECAL INFUSION



For illustrative purposes only – not actual vial

REIMBURSEMENT GUIDE

A Resource Guide for Billing and Coding

INDICATION STATEMENT

PRIALT® (ziconotide) intrathecal infusion (25 mcg/mL, 100 mcg/mL) is indicated for the management of severe chronic pain in adult 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.

IMPORTANT SAFETY INFORMATION

WARNING: NEUROPSYCHIATRIC ADVERSE REACTIONS

PRIALT intrathecal infusion 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.

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Please see additional safety information on page 2.

Please see accompanying full Prescribing Information, including Boxed Warning

ADDITIONAL SAFETY INFORMATION

CONTRAINDICATIONS

PRIALT is contraindicated in patients with:

- A known hypersensitivity to ziconotide or any of its formulation components.
- Any other concomitant treatment or medical condition that would render intrathecal administration hazardous, such as the presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of cerebrospinal fluid (CSF).
- A pre-existing history of psychosis.

WARNINGS AND PRECAUTIONS

Cognitive and Neuropsychiatric Adverse Reactions

Severe psychiatric symptoms and neurological impairment may occur during treatment. Monitor all patients frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. PRIALT may cause or worsen depression, with the risk of suicide in susceptible patients. In clinical trials, 12% of patients reported hallucinations; other acute psychiatric events included paranoid reactions (3%), hostility (2%), delirium (2%), psychosis (1%), and manic reactions (0.4%). Patients with pretreatment psychiatric disorders may be at an increased risk. Management of psychiatric complications may need to include discontinuation of PRIALT, treatment with psychotherapeutic agents and/or short-term hospitalization. In clinical trials, cognitive adverse reactions included confusion (33%), memory impairment (22%), speech disorder (14%), aphasia (12%), thinking abnormal (8%), and amnesia (1%). Cognitive impairment may appear gradually after several weeks of treatment. Reduce the dose of PRIALT or discontinue the use of PRIALT if signs or symptoms of cognitive impairment develop, but other contributing causes must also be considered. The cognitive effects of PRIALT are generally reversible within 2 weeks after drug discontinuation. The elderly (≥ 65 years) are at higher risk for confusion. Concomitant use of central nervous system (CNS) depressants with PRIALT may have additive effects.

Meningitis and Other Infections

Meningitis can occur due to inadvertent contamination of the microinfusion device and other means. In clinical trials, the rate of meningitis was 3% (40 cases) in the PRIALT group using either internal or external microinfusion devices and 1% (1 case) with placebo. In patients with external microinfusion devices and catheters, meningitis occurred in 38 out of 41 patients (93%), 37 of whom received PRIALT and one who received placebo. Patients, caregivers, and healthcare providers must be particularly vigilant for the signs and symptoms of meningitis including, but not limited to, fever, headache, stiff neck, altered mental status (e.g., lethargy, confusion, disorientation), nausea or vomiting, and occasionally seizures. Strict aseptic procedures must be used during the preparation of the PRIALT solution and refilling of the microinfusion device.

Reduced Level of Consciousness

In clinical trials, 2% of PRIALT-treated patients became unresponsive or stuporous. If reduced levels of consciousness occur, discontinue PRIALT until the event resolves, and other etiologies (e.g., meningitis) must be considered.

Elevation of Serum Creatine Kinase

In clinical trials, serum creatine kinase (CK) levels above the upper limit of normal (ULN) were reported in 40% of patients, with 11% of patients having CK levels >3 times ULN. Incidences were higher during the first 2 months of treatment. Serum CK should be monitored periodically. In the setting of new neuromuscular symptoms, evaluate patients, obtain CK measurements, and if symptoms continue and CK levels remain elevated or continue to rise, reduce the dose or discontinue the use of PRIALT.

Withdrawal From Opiates

PRIALT is not an opiate and cannot prevent or relieve the symptoms associated with the withdrawal of opiates. To avoid withdrawal syndrome when opiate withdrawal is necessary, do not abruptly reduce or withdraw opioid medications.

Driving and Operating Machinery

Use of PRIALT has been associated with cognitive impairment and decreased alertness/unresponsiveness. Caution patients against engaging in hazardous activities that require complete mental alertness or motor coordination.

MOST COMMON ADVERSE REACTIONS

The most frequently reported adverse reactions ($\geq 5\%$) in clinical trials ($n=1254$ PRIALT-treated patients) were dizziness, nausea, confusional state, and nystagmus. Slower titration of PRIALT may result in fewer serious adverse reactions and discontinuations for adverse reactions.

To report suspected adverse reactions, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact TerSera Therapeutics at 1-844-334-4035 or medicalinformation@tersera.com

Please see accompanying full prescribing information, including BOXED WARNING.

Packaging and Billing Information

PRIALT® (ziconotide) Intrathecal Infusion Packaging and Medicare Billing in Physician (Place of Service [POS] Code 11) and Outpatient Settings (POS Codes 19, 22, & 24)^{1,2}

PRIALT Packaging Information					Medicare Billing in Physician Office Setting and Outpatient Setting		Medicare Billing in Outpatient Setting
NDC#	Vials (Number x Volume)	Total Volume in Vial	Concentration	Total Drug Quantity	HCPCS Codes and Description	Billing Units (Per 1 mcg)	APC Code
70720-0723-10	1 x 20 mL	20 mL	25 mcg/mL	500 mcg	J2278 Injection, ziconotide, 1 mcg	500	1694
70720-0722-10	1 x 5 mL	5 mL	100 mcg/mL	500 mcg	J2278 Injection, ziconotide, 1 mcg	500	1694
70720-0720-10	1 x 1 mL	1 mL	100 mcg/mL	100 mcg	J2278 Injection, ziconotide, 1 mcg	100	1694

Special Notes

According to the Medicare Claims Processing Manual, chapter 17, section 40, "Discarded Drugs and Biologicals," if a physician must discard the remainder of a vial after administering a dose to a Medicare patient, the program covers the amount discarded along with the amount administered. The coverage of discarded drugs applies only to single-use vials.³ For drug amounts discarded/not administered to the patient, Centers for Medicare & Medicaid Services states that Medicare contractors may require the use of modifier J. Modifier JW is used to identify unused drugs or biologics from single-use vials or single-use packages that are appropriately discarded. Modifier JZ is used to attest that no amount of drug was discarded and eligible for payment.^{4,5}



Please see accompanying full prescribing information, including BOXED WARNING.

Physician Office Setting

Physician Office Billing Codes (Place of Service [POS] Code 11)^{1,2}

CPT/HCPCS Codes	Code Description
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified healthcare professional)
J2278	Injection, ziconotide, 1 mcg
A4220	Refill kit for implantable infusion pump

Physician CPT Code Modifiers^{4,5,b}

Modifier	Modifier Description
-KD	Drug or biological infused through durable medical equipment (DME)
-JW	Drug amount discarded/not administered to any patient
-JZ	Zero drug amount discarded/not administered to any patient

^a Coding Tip: Instructions for Use of the CPT Codebook²:

When advanced practice nurses and physician assistants are working with physicians, they are considered as working in the exact same specialty and exact same subspecialties as the physician. A "physician or other qualified healthcare professional" is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that professional service. These professionals are distinct from "clinical staff." A clinical staff member is a person who works under the supervision of a physician or other qualified healthcare professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but does not individually report that professional service. Other policies may also affect who may report specific services.

^b Contact your Medicare contractor and/or all other contracted/non-contracted payer(s) for any questions regarding filing guidelines or coverage, coding, and payment direction.

Special Note²

The place of service codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payers (e.g., Medicare, Medicaid, other private insurance) for reimbursement policies regarding these codes.

Place of Service 11 refers to an office location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.

Please see accompanying full prescribing information, including BOXED WARNING.

Physician Office Setting

Sample Medicare Claim Form: CMS-1500 Form (Physician Office)

The healthcare provider is responsible for determining appropriate codes for an individual patient for related and/or separate procedures and for completing the appropriate forms.

1 Field 19

Billing with a specific HCPCS code allows for faster payment through electronic billing. Manual billing may still be required in certain circumstances. In those cases it may be necessary to provide the following information (see line 19) for payment: Specify drug information, ie, drug name, NDC, dosage, strength, and route of administration. Please note that for billing purposes, the NDC requires 11 digits (thus a zero has been entered into the sixth digit). This is consistent with the Red Book and First DataBank listings.

2 Field 21

Enter the appropriate ICD-10-CM diagnosis code. Additional diagnosis codes may apply.

Field 24, Column D

3 Enter the appropriate HCPCS codes and CPT codes.

PRIALT® (ziconotide)

J2278 ziconotide intrathecal infusion: Please check your local payer's coverage and coding guidelines regarding the use of modifiers.

Field 24, Column G

4 Enter the number of units billed that corresponds to the vial size used. J2278 is billed per 1 mcg. Depending on the vial administered, 100 or 500 units should be reported. Contact your Medicare contractor and/or all other contracted/non-contracted payer(s) for any questions regarding filing guidelines or coverage, coding, and payment.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare) ☒ MEDICAID (Medicaid) ☐ TRICARE (TRICARE) ☐ CHAMPVA (Champion) ☐ GROUP HEALTH PLAN (Group Health Plan) ☐ FECA (FECA) ☐ OTHER (Other) ☐

2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE (MM/DD/YY) 4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No. Street) 6. PATIENT RELATIONSHIP TO INSURED (Self, Spouse, Child, Other) 7. INSURED'S ADDRESS (No. Street)

8. RESERVED FOR NUCC USE 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) 10. IS PATIENT'S CONDITION RELATED TO: 11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.) 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) 15. OTHER DATE 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) 20. OUTSIDE LAB? 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Please enter A-L to service line below (41E) ICD-10-CM) 22. REQUISITION CODE 23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From To B. PROCEDURE, SERVICE, OR SUPPLY (Explain Unusual Circumstances) C. DIAGNOSIS (ICD-10-CM) D. CHARGES (NPI) E. CHARGES (NPI) F. CHARGES (NPI) G. CHARGES (NPI) H. CHARGES (NPI) I. CHARGES (NPI) J. CHARGES (NPI)

25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (No prior bills on file) 28. TOTAL CHARGE 29. AMOUNT PAID 30. Refs for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER (I certify that the statements on the reverse apply to this bill and are made a part thereof.) 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH #

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED CMS-0938-1197 FORM 1500 (02-12)

As of April 1, 2014, version 02/12 is required.

^a CMS Manual System, Publication 100-4, Medicare Claims Processing Manual, chapters 17 (Rev. 2437, 04-04-12) and 20 (Rev. 2464, 05-04-12), addresses the payment of claims for infusion drugs furnished through an implanted DME infusion pump.³

Please see accompanying full prescribing information, including **BOXED WARNING**.

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Hospital Outpatient and Ambulatory Surgical Center Setting

Hospital Outpatient and Ambulatory Surgical Center Billing Codes (Place of Service [POS] Codes 19, 22, & 24)^{1,2}

CPT/HCPCS Codes	Code Description	APC Code	Status Indicator ^a
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill	5743	S
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified healthcare professional)	5743	S
J2278	Injection, ziconotide, 1 mcg	1694	K
A4220	Refill kit for implantable infusion pump	—	N

^a Status Indicator⁶:

K = Non-pass-through drugs and nonimplantable biologicals

N = Items and services packaged into APC rates

S = Significant procedure, not discounted when multiple

^b Coding Tip: Instructions for Use of the CPT Codebook²:

When advanced practice nurses and physician assistants are working with physicians, they are considered as working in the exact same specialty and exact same subspecialties as the physician. A "physician or other qualified healthcare professional" is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that professional service. These professionals are distinct from "clinical staff." A clinical staff member is a person who works under the supervision of a physician or other qualified healthcare professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but does not individually report that professional service. Other policies may also affect who may report specific services.

CMS Manual System, Publication 100-4, Medicare Claims Processing Manual, chapters 17 (Rev. 2437, 02-2024) and 20 (Rev. 2464, 05-2024), addresses the payment of claims for infusion drugs furnished through an implanted DME infusion pump.³

Special Note²

The place of service codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payers (e.g., Medicare, Medicaid, other private insurance) for reimbursement policies regarding these codes.

Site of service 19 refers to a portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

Site of service 22 on campus-outpatient hospital refers to a portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

Site of service 24 Ambulatory Surgical Center refers to a freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis.

Please see accompanying full prescribing information, including BOXED WARNING.

Hospital Outpatient and Ambulatory Surgical Center Setting

Sample Medicare Claim Form: CMS-1450 Form (Hospital Outpatient)

The healthcare provider is responsible for determining appropriate codes for an individual patient for related and/or separate procedures and for completing the appropriate forms.

- 1 Fields 42 and 43**
Enter the appropriate revenue codes and descriptions corresponding to HCPCS codes in field 44
Other revenue codes may be acceptable and vary by location.
- 2 Field 44**
Enter the appropriate HCPCS and CPT codes. PRIALT® (ziconotide) intrathecal infusion will be reported with HCPCS code J2278 which will map to APC 1694 for separate payment.
- 3 Field 46**
Enter the number of units billed that corresponds to the vial size used. J2278 is billed per 1 mcg. Depending on the vial administered, 100 or 500 units should be reported. Contact your Medicare contractor and/or all other contracted/non-contracted payer(s) for any questions regarding filing guidelines or coverage, coding, and payment.
- 4 Field 74**
Enter the appropriate ICD-10-CM diagnosis code. Additional diagnosis codes may apply.
- 5 Field 80**
Billing with a specific HCPCS code allows for faster payment through electronic billing. Manual billing may still be required in certain circumstances. In those cases it may be necessary to provide the following information for payment: Report the NDC, quantity of the drugs administered (expressed in unit of measure applicable to the drug or biological), and the date the drug was administered to the patient.

^a CMS Manual System, Publication 100-4, Medicare Claims Processing Manual, chapters 17 (Rev. 2437, 04-04-12) and 20 (Rev. 2464, 05-04-12), addresses the payment of claims for infusion drugs furnished through an implanted DME infusion pump.³

References

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