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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IMPORTANT SAFETY INFORMATION, (continued)

PRIALT® (ziconotide) 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 IT 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 preexisting history of psychosis.

Advise patients of the signs and symptoms of meningitis, such as fever, headache, stiff neck, altered mental status, nausea, vomiting, and occasionally seizures. Reduced levels of consciousness and creatine kinase (CK) elevations have occurred in patients taking PRIALT. Monitor serum CK periodically. For patients being withdrawn from intrathecal opiates, gradually taper over a few weeks and replace with a pharmacologically equivalent dose of oral opiates. The most frequently reported adverse reactions (≥25%) 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.

PRIALT is not intended for intravenous (IV) administration. PRIALT is for use only in the Medtronic SynchroMed® II Infusion System and the CADD-Micro Ambulatory Infusion Pump.

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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
18860-0723-10	1 x 20 mL	20 mL	25 mcg/mL	500 mcg	J2278 Injection, ziconotide, 1 mcg	500	1694
18860-0722-10	1 x 5 mL	5 mL	100 mcg/mL	500 mcg	J2278 Injection, ziconotide, 1 mcg	500	1694
18860-0720-10	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]

Drug amount discarded/not administered to the patient. Centers for Medicare & Medicaid Services states that Medicare contractors may require the use of modifier JW. Modifier JW is used to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded.[4,5]

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PRIALT® (ZICONOTIDE) INTRATHECAL INFUSION

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 the patient. Centers for Medicare & Medicaid Services states that Medicare contractors may require the use of modifier JW. Modifier JW is used to identify unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded.

[a] Coding Tip: Instructions for Use of the CPT Codebook[2]:
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 filling guidelines for coverage, coding, and payment direction.

Special Note[2]

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.

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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.

3 Field 24, Column D

Enter the appropriate HCPCS codes and CPT codes.

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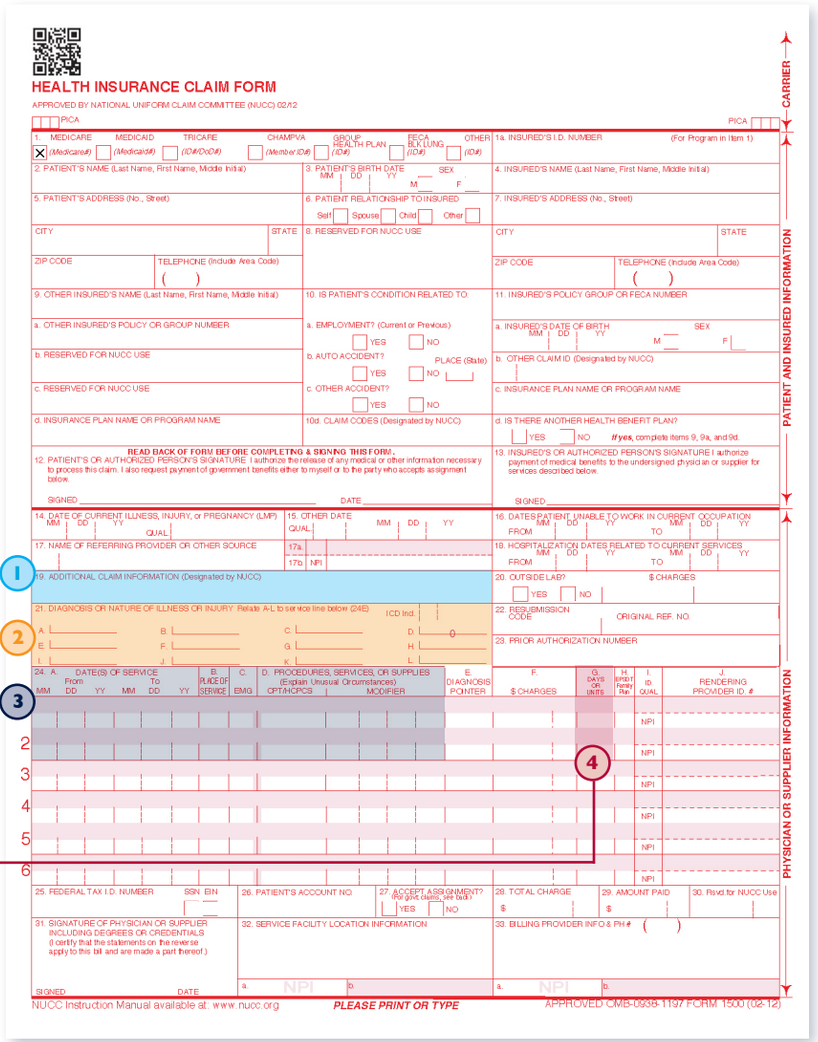
J2278 ziconotide intrathecal infusion: Please check your local payer's coverage and coding guidelines regarding the use of modifiers.

4 Field 24, Column G

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 filling guidelines for coverage, coding, and payment.



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]

Reimbursement information provided by TerSera Therapeutics LLC is gathered from third-party sources and is presented for illustrative purposes only. This information does not constitute reimbursement or legal advice, and TerSera Therapeutics LLC makes no representation or warranty regarding this information or its completeness, accuracy, or timeliness. Laws, regulations, and payer policies concerning reimbursement are complex and change frequently, and service providers are responsible for all decisions relating to coding and reimbursement submissions. Accordingly, TerSera Therapeutics LLC strongly recommends that you consult with your payers, reimbursement specialist, and/or legal counsel regarding coding, coverage, and reimbursement matters.

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PRIALT® (ZICONOTIDE) INTRATHECAL INFUSION

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, 1mcg	1694	K
A4220	Refill kit for implantable infusion pump	–	N

[a] Status Indicator[6]:
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 Codebook[2]:
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, 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]

Special Note[2]

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.

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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.

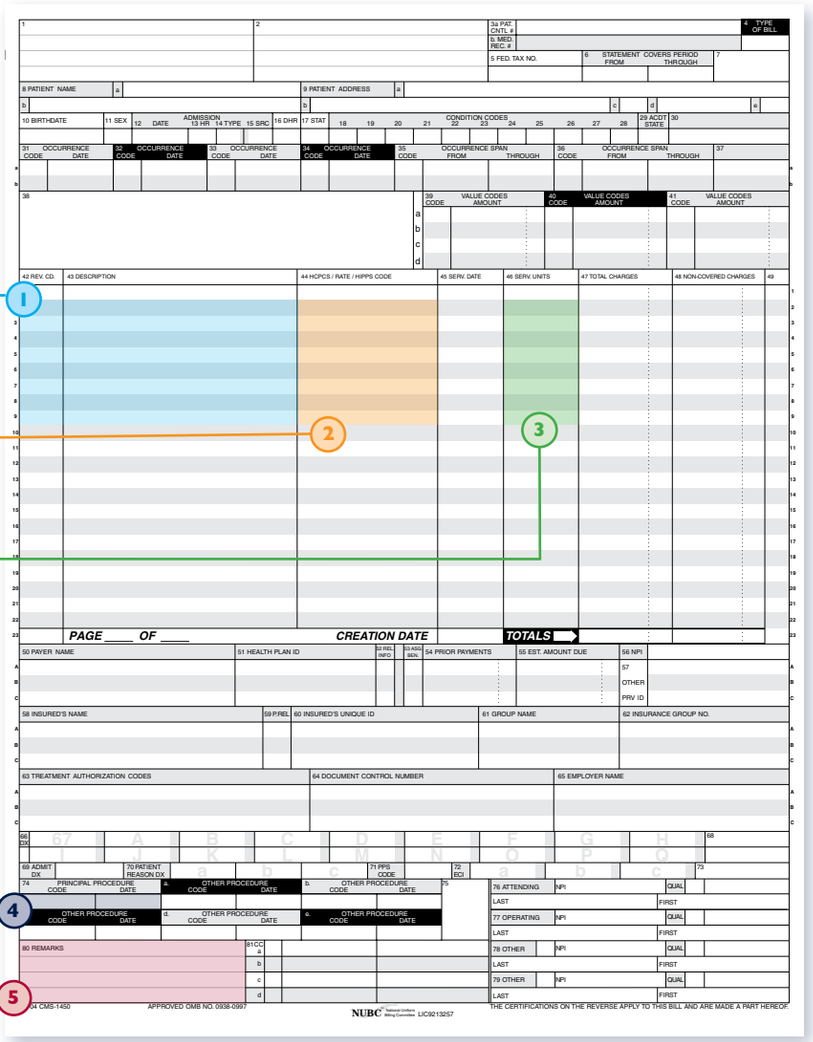
1 **Fields 42 and 43**
Enter the appropriate revenue codes and descriptions corresponding to HCPCS codes in field 44.
Other revenue codes may be acceptable and vary by location.

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 filling guidelines for 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]

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References

1. Addendum B – Final OPPS payment by HCPCS code for CY 2019. Centers for Medicare and Medicaid Services website. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates-Items/2019-January-Addendum-B.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending. Updated January 2019. Accessed February 9, 2019.
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5. DME MAC Jurisdiction C supplier manual. Chapter 16. CGS website. https://cgsmedicare.com/jc/pubs/pdf/chpt16.pdf. Updated January 2, 2019. Accessed February 9, 2019.
6. Addendum D1 – Proposed OPPS payment status indicators. Centers for Medicare and Medicaid Services website. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/CMS-1404-P_AddD1.pdf. Updated April 10, 2018. Accessed December 27, 2018.

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