SAMPLE LETTER OF MEDICAL NECESSITY
[To be completed by prescriber and printed on letterhead]

[Date]

[Name of Health Insurance Company]
[Attn:]
[Address]
[City, State, Zip]

Re: Letter of Medical Necessity for PRIALT (ziconotide) solution, intrathecal infusion

Patient: [Patient Name]
Group/policy Number: [Number]
Date(s) of service: [Dates]
Diagnosis: [Code & Description]

Dear [Insert contact name or department]:

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with PRIALT (ziconotide) solution, intrathecal infusion.

The code for PRIALT is J2278 and J2278 including when billed with modifiers JW and KD.

PRIALT (ziconotide) solution, intrathecal infusion has received approval for the treatment of the following indication:

- PRIALT (ziconotide) solution, intrathecal infusion is an N-type calcium channel antagonist indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or intrathecal morphine.

PRIALT is a non-opioid, intrathecal option for adult patients who suffer from severe chronic pain for whom intrathecal therapy is warranted. PRIALT (ziconotide) binds to N-type calcium channels located on the primary nociceptive (A-δ and C) afferent nerves in the superficial layers (Rexed laminae I and II) of the dorsal horn in the spinal cord. Although the mechanism of action of ziconotide has not been established in humans, results in animals suggest that its binding blocks N-type calcium channels, which leads to a blockade of excitatory neurotransmitter release from the primary afferent nerve terminals and antinociception.

- Initiate dosing with PRIALT via intrathecal device at no more than 2.4 mcg/day (0.1 mcg/hr).
- Titrate doses by up to 2.4 mcg/day (0.1 mcg/hr) at intervals of no more than 2 to 3 times per week based on analgesic response and adverse events. Dose increases in increments of less than 2.4 mcg/day (0.1 mcg/hr) and less frequently than 2 to 3 times per week may be used. For each dose titration, assess the dosing requirements and adjust the pump infusion flow rate as required to achieve the new dosing.
- The maximum recommended dose is 19.2 mcg/day (0.8 mcg/hr).

This letter serves to document that [PATIENT NAME] has a diagnosis of [DIAGNOSIS] and needs treatment with PRIALT, and that PRIALT is medically necessary for [him/her] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatment.

Patient Medical History and Diagnosis:
[PATIENT NAME] is a [AGE]-year-old [MALE/FEMALE] diagnosed with [DIAGNOSIS]. [NAME OF PATIENT] has been in my care since [DATE]. As a result of the primary diagnosis [DIAGNOSIS], and underlying condition diagnosis my patient [ENTER BRIEF DESCRIPTION OF PATIENT HISTORY]. Additionally, [PATIENT] has tried [PREVIOUS THERAPIES] and [OUTCOMES]. The attached medical records document [PATIENT NAME]'s clinical condition and medical necessity for treatment with PRIALT.

Based on the above facts, I am confident that you will agree that PRIALT is indicated and medically necessary for this patient. The plan of treatment is to start the patient on PRIALT and monitor and follow up as appropriate.

Please consider approval of PRIALT on [PATIENT NAME]'s and subsequent payment for PRIALT as planned. Please refer to the enclosed Prescribing Information for PRIALT. If you have any further questions regarding this matter, please do not hesitate to call me at [PHYSICIAN TELEPHONE NUMBER]. Thank you for your prompt attention to this matter.

Sincerely,
[PHYSICIAN NAME]
[PROVIDER IDENTIFICATION NUMBER]

Enclosures: (Attach as appropriate)

Please see Full Prescribing Information, Including Boxed Warning

INDICATION

PRIALT® (ziconotide) solution, intrathecal infusion 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 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.

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 (≥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.