



POLICIES AND PROCEDURE MANUAL

Policy: MBP 58.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Prialt (ziconotide intrathecal infusion)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Prialt (ziconotide intrathecal infusion)

II. Purpose/Objective:

To provide a policy of coverage regarding Prialt (ziconotide intrathecal infusion)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Prialt (ziconotide intrathecal infusion) is a non-opioid and non-NSAID analgesic categorized as an N-type calcium channel blocker (NCCB). Ziconotide selectively binds to N-type voltage-sensitive calcium channels located on the nociceptive afferent nerves of the dorsal horn in the spinal cord. This binding is thought to block N-type calcium channels, leading to a blockade of excitatory neurotransmitter release and reducing sensitivity to painful stimuli.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Prialt (ziconotide intrathecal infusion) is considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business for the management of severe chronic pain in insured individuals 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, when ALL of the following criteria are met:

- Physician provided documentation of inadequate response to or intolerance to systemic analgesics, adjunctive therapies, AND intrathecal morphine **AND**
- Physician provided documentation that the recommendation for the use of Prialt has been made by a minimum of two independent pain management specialists **AND**
- Physician provided documentation that the insured individual has been evaluated by a licensed behavioral/mental health professional to rule out pre-existing history of psychosis **AND**
- Physician provided documentation that the insured individual has been counseled and acknowledges understanding of the potential risk of psychosis or neurological impairment and wishes to proceed with this treatment option.

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **6 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued need for IT therapy and evidence of pain control. The medication will no longer be covered if patient experiences toxicity or worsening of pain control.

LIMITATIONS:

Prialt carries a black box warning that severe psychosis and neurological impairment may occur during treatment. Insured individuals with a pre-existing history of psychosis should not be treated with Prialt.

Contraindications to the use of IT analgesia include conditions such as the presence of infection at the microinfusion injection site, uncontrolled bleeding diathesis, and spinal canal obstruction that impairs circulation of CSF

Prialt (ziconotide intrathecal infusion) is considered medically necessary for the Medicare line of business for the management of severe chronic pain in insured individuals 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, when ALL of the following criteria are met:

- Physician provided documentation of inadequate response to or intolerance to systemic analgesics, adjunctive therapies, OR intrathecal morphine **AND**
- Physician provided documentation that the recommendation for the use of Prialt has been made by a minimum of two independent pain management specialists **AND**
- Physician provided documentation that the insured individual has been evaluated by a licensed behavioral/mental health professional to rule out pre-existing history of psychosis **AND**
- Physician provided documentation that the insured individual has been counseled and acknowledges understanding of the potential risk of psychosis or neurological impairment and wishes to proceed with this treatment option.

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Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Prialt [prescribing information]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/25/05

Revised: 5/08 (added criteria), 01/15 (added auth duration), 8/19/22 (Medicaid PARP statement), 8/18/23 (LOB carve out, Medicaid business segment), 12/31/23 (references added), 8/8/24 (description updated, LOB table, taglines)

Reviewed: 8/09, 8/10, 8/11; 1/14; 1/20/15, 3/16, 1/31/17, 10/31/17, 9/28/18, 8/29/19, 8/26/20, 8/19/21

MA UM Committee approval: 12/31/23