Criteria for Nonformulary Use of Ziconotide for Intrathecal Infusion

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations.

A summary of the literature review used to support the criteria for non-formulary use of intrathecal ziconotide is available at http://www.vapbm.org.

Facilities should consider using a review committee to evaluate requests to prescribe intrathecal ziconotide.

VA Inclusion Criteria for Use

Patients who meet ALL of the following criteria (answers are *Yes*) may receive intrathecal (IT) ziconotide:	**YES**	**NO**
Patient is under the care of a pain specialist or anesthesiologist who has experience in the management of IT pain medications and has the resources to provide 24/7 care for problem management.	☐	☐
Patient has chronic cancer or noncancer pain	☐	☐
Patient has had documented inadequate response, intolerable adverse effects, or contraindication to ❑ systemic opioids plus adjuvant agents (e.g., antidepressants and/or antiepileptics) OR IT morphine (maximum tolerated dose not exceeding 15 mg/d) OR off-label IT hydromorphone (maximum tolerated dose not exceeding 10 mg/d)[2] (in IT or epidural screening or treatment) AND ❑ IT clonidine AND ❑ IT bupivacaine AND ❑ a combination of IT analgesics	☐	☐
Patient has or will have an implanted Medtronic SynchroMed® EL or SynchroMed® II Infusion System, or Simms Deltec CADD Micro® External Microinfusion Device and Catheter.	☐	☐
For noncancer pain, patient has received psychological evaluation (to help promote good therapeutic outcomes from IT therapy).	☐ *(Yes or N/A)*	☐

VA Exclusion Criteria

Patients who meet any of the following criteria (any answer is *Yes*) should NOT receive IT ziconotide	**Yes**	**No**
Contraindication to IT ziconotide therapy: ❑ Previous history of psychosis. ❑ Any other concomitant treatment or medical condition that would render IT administration hazardous (e.g., infection at the microinfusion injection site, uncontrolled bleeding diathesis, spinal canal obstruction that impairs circulation of CSF). ❑ Concomitant IT chemotherapy. ❑ Hypersensitivity to ziconotide or formulation components.	☐	☐
Active suicidal or homicidal behavior, major uncontrolled depression or anxiety, or serious cognitive deficits.	☐	☐

Discontinuation Criteria

NO improvement in either pain or functional ability during the first 3 weeks of IT ziconotide therapy.

Weigh Risks Versus Benefits

Patients with refractory pain will very likely require concomitant therapy with systemic or IT analgesics. Weigh the potential risks and benefits before deciding to use IT ziconotide concomitantly with IT opioids or other IT agents, such as bupivacaine, clonidine, and baclofen. The stability of these analgesics in admixtures is unknown. The efficacy and safety of only ziconotide monotherapy has been evaluated in clinical trials.

Consider potential risks versus benefits of using IT ziconotide in patients who do not have timely access to medical facilities, lack family or social support to assist with patient monitoring at home, and would have difficulty adhering to follow-up visits.

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