09-J1000-31

Original Effective Date: 01/15/11

Reviewed: 5/14/14

Revised: 02/15/16

Subject: Intrathecal Drug Therapy for Long-Term Pain Management

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Intraspinal (i.e. intrathecal, epidural) drug infusion therapy offers an effective alternative for pain control when spinal-acting analgesics or antispasmodics administered orally or transdermally do not achieve adequate pain control or are associated with unacceptable side effects or toxicities. Implanted intrathecal drug-delivery systems (IDDSs) are used to administer medication into the vicinity of the spinal cord or into the epidural space and requires diffusion of the drug through the dura to produce an effect and exposes the spinal nerve roots to the drug. Evidence in the literature suggests the principal benefit of intraspinal delivery appears to be the reduction in opioid side effects, rather than improved analgesia, although patients have reported improved pain scores in clinical trials. Additionally, intraspinal administration allows a reduction of the amount of the drug administered in comparison to oral or parenteral routes of administration. Although close monitoring is required, titration of the drugs can be performed more rapidly, allowing for more aggressive pain control with reduction of side effects and toxicities.

POSITION STATEMENT:

I. A **preliminary trial** of intrathecal or epidural administration of opiate or non-opiate analgesics for the treatment of severe, chronic intractable pain conditions of malignant and non-malignant origin meets **the definition of medical necessity** when **ALL** of the following criteria are met:

   1. The member's life expectancy is at least 3 months

2. The member has experienced failure of, or has intolerance or contraindications to, an adequate trial (i.e., six weeks or longer) of noninvasive methods of pain control, including systemic opioids administered in adequate doses with a fixed schedule (not PRN)
3. Medical contraindications to implantable devices have been eliminated (e.g., coagulopathies, infection)

Approval Duration: 1 month

II. **Permanent intrathecal or epidural administration** of opiate or non-opiate analgesics for the treatment of severe, chronic intractable pain conditions of malignant and non-malignant origin **meets the definition of medical necessity** when **BOTH** of the following criteria are met:

1. A preliminary trial of intrathecal or epidural administration of opioid drug administration was tolerated and successful as evidenced by acceptable degree of pain relief and improved function (e.g., 50% reduction in pain)
2. All of the criteria for a preliminary trial of intrathecal or epidural administration are met

Approval Duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

Most of the medication concentrations and combinations administered through IDDSs are not commercially available and therefore must be compounded in a pharmacy. Medications used in implantable drug delivery systems may include opioids, local anesthetics, adrenergic agonists, and other agents. First line opioid analgesics include morphine and hydromorphone (Dilaudid®), which have clear support from data and extensive clinical experience.

The second line treatment options may be chosen as first line options in cases where a member has predominantly neuropathic symptoms. Acceptable second line options include hydromorphone or morphine in combination with bupivacaine or clonidine. There is little evidence to support the efficacy of clonidine or bupivacaine as single agents.

Other treatment approaches, which are usually considered third-line include: 1) the combination of morphine, bupivacaine, and clonidine; 2) a switch to an alternative opioid, specifically fentanyl or sufentanil; 3) a combination of an alternative opioid, usually hydromorphone but possibly fentanyl or sufentanil, and one of the non-opioid second-line drugs, specifically bupivacaine or clonidine.

Baclofen has been approved for intrathecal use and is effective for spasticity. There is evidence that it can help when pain is specifically related to spasticity, but evidence that it has a broader analgesic effect is lacking.

The table below indicates recommended intrathecal dosing and maximum concentrations for compounded pain prescriptions.

Recommended Medication Doses and Concentrations for Intrathecal Therapy*

Drug	Standard Vial Concentration(s)	Maximum Recommended Compounded Concentration	Max Daily Dose
Baclofen	50 µg/mL, 0.5 mg/mL, 2 mg/mL	2 mg/mL	2 mg
Bupivacaine hydrochloride	0.25%, 0.5%, 0.75%	38 mg/mL	30 mg
Clonidine	100 µg/mL, 500 µg/mL	2 mg/mL	1.5 mg
Fentanyl	50 µg/mL	50 µg/mL	****
Hydromorphone hydrochloride **	1 mg/mL, 2 mg/mL, 4 mg/mL	30 mg/mL	10 mg
Morphine	0.5 mg/mL, 1 mg/mL	30 mg/mL	15 mg

* Adapted from **Ghafoor, VL et al,** Am J of Health Sys Pharm., 2007

** No preservative-free injection available.

PRECAUTIONS:

Medication errors are a common complication in intrathecal pump drug delivery. Drug refills must be done by trained individuals who are able to accurately assess pain, conduct physical examinations, and assess subtle changes in condition. It is also important that pain management centers must be extremely vigilant about their source of medications.

Dosage adjustments must be conducted in a medically supervised and adequately equipped environment. In addition, close monitoring is recommended when adjusting concentrations of the drug(s).

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding:

A4220	Refill kit for implantable infusion pump
C1772	Infusion pump, programmable (implantable) [for outpatient facility services]

C1891	Infusion pump, nonprogrammable, permanent (implantable) [for outpatient facility services]
C2626	Infusion pump, nonprogrammable, temporary (implantable) [for outpatient facility services]
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.
E0783	Infusion pump, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.
E0785	Infusion intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
J0475	Injection, baclofen, 10 mg
J0735	Injection, clonidine hydrochloride, 1 mg
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg
J2278	Injection, ziconotide, 1 mcg
J3490	Miscellaneous drugs
J7999	Compounded drug, not otherwise classified

***NOTE: All compounded prescriptions containing any of the above drugs must be submitted with a J3490 code.**

ICD-10 Diagnosis Codes That Support Medical Necessity:

G24.01	Drug induced subacute dyskinesia
G24.1	Genetic torsion dystonia
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.5	Blepharospasm
G24.8	Other dystonia
G24.9	Dystonia, unspecified
G25.89	Other specified extrapyramidal and movement disorders

G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.3	Athetoid cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
G81.10	Spastic hemiplegia affecting unspecified side
G81.11	Spastic hemiplegia affecting right dominant side
G81.12	Spastic hemiplegia affecting left dominant side
G89.21	Chronic pain due to trauma
G89.22	Chronic post-thoracotomy pain
G89.28	Other chronic postprocedural pain
G89.3	Neoplasm related pain (acute) (chronic)
R25.0	Abnormal head movements
R25.1	Tremor, unspecified
R25.2	Cramp and spasm
R25.3	Fasciculation
R25.9	Unspecified abnormal involuntary movements

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products:

The following National Coverage Determination (NCD) was reviewed on the last guideline revised date: *Infusion pumps, (280.14)* located at cms.gov.

The following Local Coverage Determination (LCD) was reviewed on the last guideline revised date: *Implantable infusion pump for the treatment of chronic intractable pain, (L31254)* located at fcso.com.

DEFINITIONS:

Epidural: situated within the spinal canal, on or outside the dura mater (tough membrane surrounding the spinal cord).

Intrathecal: into or within the subarachnoid space of the spinal column.

RELATED GUIDELINES:

Unclassified Codes and Compounded Drug Products, 09-J0000-58

OTHER:

None applicable.

REFERENCES:

1. Albright AL, Gilmartin R, Swift D, et al. Long-term intrathecal baclofen therapy for severe spasticity of cerebral origin. J Neurosurg. 2003; 98(2):291-295.
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3. Deer TR, Smith HS, Burton AW et al. Comprehensive consensus based guidelines on intrathecal drug delivery systems in the treatment of pain cause by cancer pain. Pain Physician 2011;14:E283-E312.
4. Ghafoor, V.L. et al, Intrathecal Drug Therapy for Long-Term Pain Management. AJHP. Vol. 64, Issue 23, 2447-2461.
5. Hayek SM, Deer TR, Pope JE et al. Intrathecal therapy for cancer and non-cancer pain. Pain Physician 2011;14:219-48.
6. Intrathecal Fentanyl for Chronic Nonmalignant Pain, WCB Evidence Based Practice Group, Feb/2005.
7. Knight, K., et al, Implantable Intrathecal Pumps for Chronic Pain: Highlights and Updates. Croat Med J. 2007 February; 48(1): 22–34.
8. Smith HS, Deer TR, Staats PS. Intrathecal drug delivery. Pain Physician 2008;11:S89-S104.
9. Smith TJ, Staats PS, Deer T, et al. Implantable Drug Delivery Systems Study Group. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. J Clin Oncol. 2002; 20(19): 4040-4049.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 05/14/14.

GUIDELINE UPDATE INFORMATION:

01/15/11	New Medical Coverage Guideline.
10/15/11	Review and revision to guideline; consisting of updating references.
01/01/12	Revision to guideline; consisting of updating coding.
10/15/12	Review and revision to guideline; consisting of updated position statement, dosage and administration and references.
06/15/13	Review and revision to guideline; consisting of revising position statement to include approval duration and updating program exceptions section.
06/15/14	Review and revision to guideline; consisting of reformatting position statement and updating references.
01/01/15	Revision to guideline; consisting of annual HCPCS coding update
07/01/15	Revision to guideline; consisting of coding update.
11/01/15	Revision: ICD-9 Codes deleted.
01/01/16	Annual HCPCS coding update: added code J7999 and deleted code Q9977.
02/15/16	HCPCS coding update.