PROVIDER POLICIES & PROCEDURES

IMPLANTABLE INTRATHECAL AND EPIDURAL INFUSION PUMPS

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for implantable intrathecal and epidural infusion pumps. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

The implantable infusion pump (IIP) is a drug delivery system that provides continuous infusion of a medication at a constant and precise rate.

Intrathecal pumps deliver small doses of medication directly to the spinal fluid. They consist of a small battery-powered, programmable pump that is implanted under the subcutaneous tissue of the abdomen and connected to a small catheter tunneled to the site of spinal entry.

Both programmable and non-programmable infusion pumps are available. Programmable infusion pumps are used when dose titration and regulation vary due to the changing condition of the individual; while non-programmable pumps are used for fixed rate medication delivery when an individual's dosage is expected to be stable.

Prior to implanting a permanent intrathecal device providers should conduct a temporary trial to determine its benefits. During the trial, the planned drug should be infused through an indwelling catheter that may be placed in the intrathecal or epidural space.

CLINICAL GUIDELINE

Coverage guidelines for the use of implantable intrathecal and epidural infusion pumps are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only.* Coverage determinations are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Implantation

The HUSKY Health program considers implantable intrathecal or epidural infusion pumps medically necessary when:

Continuous or regular infusion of a medication is required to treat or manage a specific condition; and

1. Other forms of administration of medications have failed or were inadequate; and
2. Life expectancy is greater than three (3) months; and

3. For intrathecal placement, tumor advancement on the thecal sac has been ruled out by appropriate testing; and
4. No contraindications to implantation exist, such as sepsis or coagulopathy; and
5. A temporary trial of spinal (epidural or intrathecal) medications has been successful as defined by a 50% reduction in pain in the case of spinal analgesics, or by other objective measures appropriate to the use of other medications, prior to permanent implantation.

Note: A *temporary* trial of an intrathecal or epidural infusion pump used for the treatment of malignant pain may be considered medically necessary based on the above criteria.

All other uses of implantable intrathecal and epidural drug infusion pumps are typically considered investigational and therefore not medically necessary; however, other uses may be considered medically necessary based on an assessment of the individual and his or her unique clinical needs.

Replacement
The HUSKY Health program considers replacement of implantable infusion pumps (which may also involve upgrading to the most current technology) medically necessary when the device is no longer functioning.

Replacement or upgrades of implantable infusion pumps are typically not considered medically necessary when requested for convenience or to upgrade to newer technology when the current components remain functional; however, a replacement or upgrade may be considered medically necessary based on an assessment of the individual and his or her unique clinical needs

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization of implantable intrathecal and epidural drug infusion pumps is required. Requests for coverage of implantable intrathecal and epidural drug infusion pumps will be reviewed in accordance with procedures in place for reviewing requests for surgical procedures. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for implantable intrathecal and epidural drug infusion pumps:
1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal ; and
2. Documentation from requesting physician which includes diagnosis and clinical information supporting medical necessity; and
3. Documentation of the individual's response to temporary trial.

Note:
Medical records may be requested.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for implantable intrathecal and epidural infusion pumps for individuals covered under the HUSKY Health Program effective October 1, 2013.

LIMITATIONS
Not Applicable

CODES:

Code	Definition
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump with or without programming

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4)

not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

Peer Reviewed Publications:

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.
2. Albright AL. Intrathecal baclofen in cerebral palsy movement disorders. J Child Neurol. 1996; 11(Suppl 1):S29-35.
3. Anderson V, Burchiel KJ. A prospective study of long-term intrathecal morphine in the management of chronic nonmalignant pain. Neurosurgery. 1999; 44(2):289-300.
4. Awaad Y, Tayem H, Munoz S, et al. Functional assessment following intrathecal baclofen therapy in children with spastic cerebral palsy. J Child Neurol. 2003; 18(1):26-34.
5. Damascelli B, Patelli G, Frigerio LF, et al. First clinical experience with a high-capacity implantable infusion pump for continuous intravenous chemotherapy. Cardiovasc Intervent Radiol. 1999; 22(1):37-43.
6. Gilmer-Hill HS, Boggan JE, Smith KA, Wagner FC Jr. Intrathecal morphine delivered via subcutaneous pump for intractable cancer pain: a review of the literature. Surg Neurol. 1999; 51(1):12-15.
7. Gooch JL, Oberg WA, Grams B, et al. Care provider assessment of intrathecal baclofen in children. Dev Med Child Neurol. 2004; 46(8):548-552.
8. Krach LE, Kriel RL, Gilmartin RC, et al. Hip status in cerebral palsy after one year of continuous intrathecal baclofen infusion. Pediatr Neurol. 2004; 30(3):163-168.
9. Metz L. Multiple sclerosis: symptomatic therapies. Semin Neurol. 1998; 18(3):389-395.
10. Penn RD, Paice JA. Chronic intrathecal morphine for intractable pain. J Neurosurg 1987; 67:182-186.
11. Pohl M, Rockstroh G, Ruckriem S, et al. Time course of the effect of a bolus dose of intrathecal baclofen on severe cerebral spasticity. J Neurol. 2003; 250(10):1195-1200.
12. Prager J, Jacobs M. Evaluation of patients for implantable pain modalities: medical and behavioral assessment. Clin J Pain. 2001; 17(3):206-214.
13. 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.
14. Taricco M, Adone R, Pagliacci C, Telaro E. Pharmacological interventions for spasticity following spinal cord injury. Cochrane Database Syst Rev. 2000; (2):CD001131.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Medical Association, Current Procedural Terminology Manual: 2019

2. American Society of Anesthesiologists, Inc. Practice guidelines for chronic pain management: An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2010; 112(4) - 810-833.
3. Australian Safety and Efficacy Register of New Interventional Procedures; Surgical Implantable Spinal Infusion Devices for Chronic Pain and Spasticity. 2003; 1-46.
4. Centers for Medicare and Medicaid Services. National Coverage Determination for Infusion Pumps. NCD #280.14. Effective December 17, 2004. Available at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed on September 9, 2012.

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	September 2013	
Reviewed	September 2014	Clinical Quality Subcommittee review. Reference updated. Added CPT code 62360. Update to criteria. Added "or epidural" to statement on page 1 "The HUSKY Health program typically considers implantable intrathecal (or epidural) infusion pumps clinically appropriate for the treatment of…" These changes approved at the September 15, 2014 Clinical Quality Subcommittee meeting.
Updated	August 2015	Updated definitions for HUSKY A, B, C and D programs at request of DSS.
Reviewed	September 2015	Clinical Quality Subcommittee review. Reference updated. This change approved at the September 21, 2015 Clinical Quality Subcommittee meeting.
Updated	March 2016	Updates to language in introductory paragraph pertaining to purpose of policy. Updates to Clinical Guideline section. Updates throughout policy to reflect importance of person-centeredness when reviewing requests for these procedures. Changes approved at the March 21, 2016 Clinical Quality Subcommittee meeting. Changes approved by DSS on May 16, 2016.
Updated	January 2017	Medical Policy Committee review. Reference update. Approved by Medical Policy Committee on January 11, 2017. Approved by Clinical Quality Sub-committee on March 20, 2017. Approved by DSS on March 27, 2017.
Updated	April 2018	Medical Policy Committee review. Reference update. Approved by Medical Policy Review Committee on

		February 14, 2018. Approved by CHNCT Clinical Quality Subcommittee on March 19, 2018. Approved by DSS on April 5, 2018.
Updated	February 2019	Reference update. Change approved at the February 13, 2019 Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on March 18, 2019. Approved by DSS on March 27, 2019.