



PROVIDER POLICIES & PROCEDURES

CRANIAL REMODELING DEVICES

The primary purpose of this policy is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP Providers) with the information needed to support a medical necessity determination for cranial remodeling devices used as a treatment for infants with synostosis or moderate to severe brachiocephaly or plagiocephaly. 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.

Cranial remodeling devices are usually in the shape of an adjustable helmet or band that progressively molds the shape of the infant cranium by applying corrective forces to prominences while leaving room for growth in the adjacent flattened areas. The device may be requested for the treatment of postsurgical synostosis or positional plagiocephaly in pediatric patients.

Synostosis, a premature closure of the sutures of the cranium, may result in functional deficits secondary to increasing intracranial pressure in an abnormally or asymmetrically shaped cranium. The type and degree of craniofacial deformity depends on the type of synostosis. Synostotic deformities associated with functional deficits are addressed by surgical remodeling of the cranial vault.

Plagiocephaly refers to a misshapen head. Plagiocephaly without synostosis, also called positional or deformational plagiocephaly, can be secondary to various environmental factors including, but not limited to, premature birth, restrictive intrauterine environment, birth trauma, torticollis, cervical anomalies, and sleeping position.

Brachycephaly is a term often used to describe uniform flattening of the posterior portion of the head, a specific positional non-synostotic plagiocephaly occurring in an infant who sleeps and spends lengthy periods lying on its back. Most cases correct spontaneously after regular changes in sleeping position or following physiotherapy aimed at correcting neck muscle imbalance.

The majority of cases of plagio- or brachiocephaly are temporary cosmetic conditions that resolve spontaneously with time and movement. Although the use of a cranial remodeling device may lead to a faster resolution of a cosmetic condition, cosmetic conditions are not medically necessary and therefore cannot be covered, as set forth in Section 17b-262-998(2) of the Regulations of Connecticut State Agencies.

CLINICAL GUIDELINE

Coverage guidelines for cranial remodeling devices (remodeling bands or helmets) are made in accordance with the CT Department of Social Services (DSS) definition of Medical Necessity. The

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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:

Cranial remodeling devices (remodeling bands or helmets) may be considered medically necessary for the treatment of either synostosis, plagiocephaly or brachycephaly in children between 4 and 12 months of age when the device is custom made and fitted for the child and:

- A. The child has had surgery for craniosynostosis, and the orthosis is needed for post-operative care; **OR**
- B. The child has severe plagiocephaly or brachycephaly (cephalic index greater than or equal to 90% or a transdiagonal difference greater than 10 mm); **AND**
- C. The child is not meeting developmental milestones secondary to plagiocephaly or brachycephaly (i.e. rolling, sitting, creeping); **AND**
- D. Marked asymmetry has not been substantially improved following a two month trial of conservative treatment e.g. physical therapy, alternative positioning, "tummy time"; **AND**
- E. There is clear and detailed documentation in the medical record, submitted by the treating physician, which indicates the severity of the brachycephaly or plagiocephaly including the child's inability to meet specific developmental milestones along with the failure of conservative management.

Note: A letter generated by the DME provider and signed by the treating physician or therapist does not meet this requirement.

Second cranial remodeling devices (remodeling bands or helmets) may be considered medically necessary for the treatment of either synostosis, plagiocephaly or brachycephaly in children between 4 and 12 months of age when:

- A. The DME provider has provided justification why the current orthosis cannot be adjusted or modified: **AND**
- B. The child has had surgery for craniosynostosis, and continued use of an orthosis is needed for post-operative care; **OR**
- C. The child continues to have severe plagiocephaly or brachycephaly (cephalic index greater than or equal to 90% **OR** a transdiagonal difference greater than 10 mm); **AND**
- D. The child continues to not meet developmental milestones secondary to plagiocephaly or brachycephaly (i.e. rolling, sitting, creeping); **AND**
- E. There is clear and detailed documentation in an updated medical record, submitted by the treating physician, which indicates the severity of the brachycephaly or plagiocephaly including the child's inability to meet specific developmental milestones along with the failure of conservative management.

Note: A letter generated by the DME provider and signed by the treating physician or therapist does not meet this requirement.

The use of a cranial remodeling device for individuals not meeting the above criteria is considered cosmetic in nature and therefore not medically necessary. Services that are not medically necessary are not covered as set forth in Section 17b-262-998(2) of the Regulations of Connecticut State Agencies.

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

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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 cranial remodeling devices is required. Requests for coverage of cranial remodeling devices will be reviewed in accordance with procedures in place for reviewing requests for durable medical equipment. 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 cranial remodeling devices:

1. Fully completed State of Connecticut, Department of Social Services Outpatient Prior Authorization Request Form;
2. Documentation from the requesting physician or treating clinician which includes the diagnosis and clinical information to support medical necessity; and
3. Copies of medical records as requested.

EFFECTIVE DATE

This policy is effective for prior authorization requests for cranial remodeling devices for individuals covered under the HUSKY Health Program on or after February 1, 2018.

LIMITATIONS

N/A

HCPCS CODE:

Code	Description
S1040	Cranial remodeling orthotic, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

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).

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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. **HUSKY Plus Physical Program (or HUSKY Plus Program):** A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.
8. **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.
9. **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:

1. CMS, Health Care Procedural Coding System Level II Manual: 2017
2. Persing JA. MOC-PS(SM) CME article: management considerations in the treatment of craniosynostosis. *Plast Reconstr Surg.* Apr 2008;121(4 Suppl):1-11.
3. Kaufman BA, Muszynski CA, Matthews A, et al. The circle of sagittal synostosis surgery. *Semin Pediatr Neurol.* Dec 2004;11(4):243-248.
4. Stevens PM, Hollier LH, Stal S. Post-operative use of remoulding orthoses following cranial vault remodeling: a case series. *Prosthet Orthot Int.* Dec 2007;31(4):327-341.
5. Jimenez DF, Barone CM, Cartwright CC, et al. Early management of craniosynostosis using endoscopic-assisted strip craniectomies and cranial orthotic molding therapy. *Pediatrics.* Jul 2002;110(1 Pt 1):97-104.
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7. Jimenez DF, Barone CM. Endoscopic technique for sagittal synostosis. *Childs Nerv Syst.* Sep 2012;28(9):1333-1339.
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12. Chan JW, Stewart CL, Stalder MW, et al. Endoscope-assisted versus open repair of craniosynostosis: a comparison of perioperative cost and risk. *J Craniofac Surg*. Jan 2013;24(1):170-174.
13. van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, et al. Helmet therapy in infants with positional skull deformation: randomised controlled trial. *BMJ*. 2014;348:g2741.
14. McGarry A, Dixon MT, Greig RJ, et al. Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly. *Dev Med Child Neurol*. Aug 2008;50(8):568-576.
15. Mulliken JB, Vander Woude DL, Hansen M, et al. Analysis of posterior plagiocephaly: deformational versus synostotic. *Plast Reconstr Surg*. Feb 1999;103(2):371-380.
16. Loveday BP, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? *J Craniofac Surg*. Jul 2001;12(4):308-313.
17. Xia JJ, Kennedy KA, Teichgraeber JF, et al. Nonsurgical treatment of deformational plagiocephaly: a systematic review. *Arch Pediatr Adolesc Med*. Aug 2008;162(8):719-727.
18. Graham JM, Jr., Gomez M, Halberg A, et al. Management of deformational plagiocephaly: repositioning versus orthotic therapy. *J Pediatr*. Feb 2005;146(2):258-262.
19. Kluba S, Kraut W, Calgeer B, et al. Treatment of positional plagiocephaly--helmet or no helmet? *J Craniomaxillofac Surg*. Jul 2014;42(5):683-688.
20. Couture DE, Crantford JC, Somasundaram A, et al. Efficacy of passive helmet therapy for deformational plagiocephaly: report of 1050 cases. *Neurosurg Focus*. Oct 2013;35(4):E4.
21. Fowler EA, Becker DB, Pilgram TK, et al. Neurologic findings in infants with deformational plagiocephaly. *J Child Neurol*. Jul 2008;23(7):742-747.
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25. National Institute of Neurological Disorders and Stroke (NINDS). Craniosynostosis Information Page. 2016; <https://www.ninds.nih.gov/Disorders/All-Disorders/Craniosynostosis-Information-Page> Accessed September 2017.
26. NHS Quality Improvement. The use of cranial orthosis treatment for infant deformational plagiocephaly. Evidence Note No. 16. 2007; http://www.healthcareimprovementscotland.org/programmes/medicines_and_technologies/archived_evidence_notes/evidence_note_16.aspx Accessed September 2017.
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28. Laughlin J, Luerssen TG, Dias MS, et al. Prevention and management of positional skull deformities in infants. *Pediatrics*. Dec 2011;128(6):1236-1241.
29. Task Force on Sudden Infant Death Syndrome, Moon RY. SIDS and other sleep-related infant deaths: expansion of recommendations for a safe infant sleeping environment. *Pediatrics*. Nov 2011;128(5):1030-1039.

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	September 2017	Approved by the Medical Policy Review Committee on October 18, 2017. Approved by the Clinical Quality Subcommittee on December 18, 2017. Approved by DSS on December 22, 2017.

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