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 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:

A. For the treatment of synostotic deformities when a pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with specific expertise in the treatment of craniosynostosis has documented the need for surgical correction of craniosynostosis, and the postoperative need for a cranial orthotic;
   OR
B. For the treatment of nonsynostotic positional cranial deformity in infants between the ages of 4 to 12 months of age when:
   1. A pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with specific expertise in the treatment of craniosynostosis or nonsynostotic cranial deformity (who is not employed or contracted with a commercial orthotic company or supplier/distributor) has determined that the infant does not have craniosynostosis;
      and
   2. A pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with specific expertise in the treatment of craniosynostosis or nonsynostotic cranial deformity (who is not employed or contracted with a commercial orthotic company or supplier/distributor) has determined that the infant has a moderate to severe skull deformity (cephalic index greater than 93% or a transdiagonal difference of greater than 10 mm) that, unless corrected by a cranial orthotic, is likely to result in significant, permanent deformity;
      and
   3. For children ≤ six months of age, asymmetry has not been substantially improved following a two month trial of conservative therapy:
      a. Consisting of reducing the amount of awake time the infant spends directly supine on their back, supervised "tummy-time", re-positioning of the child's head such that the child lies opposite to the preferred position and periodically changing the location of the crib in the nursery. (Note: if the child is unable to change position or move the head side-to-side due to a documented medical condition [e.g., congenital muscular dystrophy], this portion of the criteria is not applicable;
         or
      b. For children with congenital torticollis, asymmetry has not been substantially improved following a two month trial of physical therapy;

The medical record should document the presence of A or B above.

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

NOTE: The use of a cranial remodeling device for individuals not meeting the above criteria is considered cosmetic in nature, and is therefore not medically necessary and cannot be covered by Medicaid.

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.

Services that are considered cosmetic in nature are not covered as set forth in Section 17b-262-342(12) of the Regulations of Connecticut State Agencies.

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 a pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with specific expertise in the treatment of craniosynostosis has documented the need for continued use of an orthosis for post-operative care; **OR**
C. For the treatment of nonsynostotic positional cranial deformity in infants between the ages of 4 to 12 months of age when a pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with specific expertise in the treatment of craniosynostosis or nonsynostotic cranial deformity (who is not employed or contracted with a commercial orthotic company or supplier/distributor) has determined that the infant continues to meet the criteria for a moderate to severe skull deformity (cephalic index greater than 93% or a transdiagonal difference of greater than 10 mm) that, unless corrected by a cranial orthotic, is likely to result in significant, permanent deformity.

   The medical record should document the presence of A and B or A and C (above).

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

NOTE: The use of a cranial remodeling device for individuals not meeting the above criteria is considered cosmetic in nature and therefore not medically necessary and cannot be covered by Medicaid.

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.

Services that are considered cosmetic in nature are not covered as set forth in Section 17b-262-342(12) 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 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 treating physician or treating clinician (who is not employed or contracted with a commercial orthotic company or supplier/distributor) which includes the diagnosis and clinical information to support medical necessity including anthropometric measurements; 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 remolding 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).
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: 2019
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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.
8. Jimenez DF, Barone CM. Multiple-suture nonsyndromic craniosynostosis: early and effective management using endoscopic techniques. J Neurosurg Pediatr. Mar 2010;5(3):223-231.
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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.
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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.
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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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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.
Updated	April 2018	Updates to Clinical Guideline section. Clarified language. Added language regarding cosmetic nature of item if criteria not met. Added statutes. Changes approved at the Medical Policy Review Committee meeting on April 11, 2018. Changes approved by the CHNCT Clinical Quality Subcommittee on June 18, 2018. Approved by DSS on June 20, 2018.
Updated	June 2019	Updates to the *Clinical Guideline* section. Added need for documentation from either a pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with expertise in the treatment of craniosynostosis that there is a need for surgical correction and need for cranial orthotic postoperatively. Added "For the treatment of nonsynostotic positional cranial deformity in infants between the ages of 4 to 12 months of age when: a pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with specific expertise in the treatment of craniosynostosis or nonsynostotic cranial deformity (who is not employed or contracted with a commercial orthotic company or supplier/distributor) has determined that the infant does not have craniosynostosis; **and** A pediatric neurosurgeon, craniofacial surgeon or other board-certified physician with specific expertise in the treatment of craniosynostosis or nonsynostotic cranial deformity (who is not employed or contracted with a commercial orthotic company or supplier/distributor) has determined that the infant has a moderate to severe skull deformity (cephalic index greater than **93%** or a transdiagonal difference of greater than 10 mm) that, unless corrected by a cranial orthotic, is likely to result in significant, permanent deformity;" Changed cephalic index from 90% to 93% in guideline to correlate with measurement for moderate to severe skull deformity.

		Removed “the child is not meeting developmental milestones due to plagiocephaly or brachycephaly” from guideline.
		Expanded language in guideline as relates to trial of conservative therapy to include repositioning of child’s head to opposite the preferred position, changing location of crib in nursery. Added statement that for children unable to change position due to medical condition, this specific portion of the criteria is not applicable. Added requirement that ordering provider not be employed by or contracted with a commercial orthotic company or supplier/distributor to both Clinical Guideline and Procedure section. Changes approved at the June 12, 2019 Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on June 19, 2019. Approved by DSS on June 21, 2019.