MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Cranial Orthotics**
Policy Number	**1.01.32**
Category	**Contract Clarification**
Original Effective Date	**10/18/01**
Committee Approval Date	**06/27/02, 07/24/03, 06/24/04, 06/23/05, 06/22/06, 04/26/07, 04/24/08, 12/11/08, 12/10/09, 12/09/10, 12/08/11, 12/06/12, 12/12/13, 12/11/14, 12/10/15, 12/8/16, 12/14/17, 12/13/18, 12/12/19, 04/18/24**
Current Effective Date	**08/15/24**
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Archived Review Date	**12/16/21, 12/22/22, 12/21/23, 04/18/24**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, cranial orthotics (e.g., helmet or cranial remodeling band) are considered **medically appropriate** in children aged three (3) to 18 months old, after a failed two-month trial of conservative treatment when used to treat **ANY** of the following:
   A. Moderate-to-severe non-synostotic (positional) plagiocephaly in conditions where the axis of the skull has been rotated (i.e., cranial vault asymmetry greater than 12 mm or cranial vault asymmetry index (CVAI) greater than or equal to 6.25%);
   B. Non-synostotic (positional) plagiocephaly with torticollis;
   C. Brachycephaly, when the cranial index is less than 76% or greater than 90%.

II. Based upon our criteria and assessment of the peer-reviewed literature, cranial orthotics used in the post-surgical treatment of craniosynostosis (synostotic plagiocephaly) have been demonstrated to improve patient outcomes and, therefore, are considered **medically appropriate.**

III. Based upon our criteria and assessment of the peer-reviewed literature, cranial orthotics (e.g., helmet or cranial remodeling band) are **contraindicated** in the following situations:
   A. Hydrocephalus
   B. Craniosynostosis without prior surgical intervention

IV. Based upon our criteria and assessment of the peer-reviewed literature, cranial orthotics when used to treat non-synostotic (positional) plagiocephaly have not been demonstrated to improve patient outcomes, as their primary beneficial outcome is aesthetic, and, therefore, are considered **not medically necessary** in all other situations.

V. Based upon our criteria and assessment of the peer-reviewed literature, cranial orthotics as the sole treatment of synostotic plagiocephaly have not been medically proven to be effective and, therefore, are considered to be **not medically necessary.**

VI. Based upon our criteria and assessment of the peer-reviewed literature, replacement cranial orthotics are considered **not medically necessary**.

Refer to Corporate Medical Policy #1.01.00 Durable Medical Equipment

Refer to Corporate Medical Policy #1.01.25 Orthotics

POLICY GUIDELINES

I. Cranial index (CI) is defined as the ratio of *width ÷ length x 100.* A CI ranging from 76-90% is considered normocephalic.

II. Coverage for external prosthetic devices is contract dependent. Orthotics will only be covered if the member's subscriber contract includes an orthotic benefit or a rider for external prosthetic devices that covers orthotics.

III. Cranial orthotics (e.g., helmets) that are used primarily and customarily for convenience or safety are ineligible for coverage, even though they may have some remote, medically related use (e.g., head protection during seizures or self-injurious behavior).

DESCRIPTION

A cranial orthotic is a device used for non-invasive treatment of non-synostotic or positional plagiocephaly. It involves the use of a custom-molded orthotic device, either a helmet or band that can progressively mold the shape of the cranium.

Dynamic orthotic cranioplasty (DOC) has also been proposed as a postoperative adjunct for those undergoing surgery for synostotic plagiocephaly. Surgical treatment is typically initiated around three (3) months of age and continues for an average of six (6) to nine (9) months.

Plagiocephaly refers to an asymmetrically shaped head. Deformations of the head attributable to pre-natal or perinatal compression usually resolve in the first few months of life. The severity of deformational plagiocephaly can be determined using measurements of face and skull (e.g., skull base asymmetry, cranial vault asymmetry, cephalic index). Cranial vault asymmetry (CVA) is determined by measuring the distance from one predesignated point on the skull to another, comparing the right and left sides. Specifically, CVA is measured across the midline using spreading calipers: from the left most lateral point on the head (eurion) to the anterior prominence of the right most lateral point on the frontozygomatic suture (frontozygomaticus) and then repeating the measurement on the opposite side. Mortenson and Steinbok (2006) defined a CVA as normal <3 mm, mild/moderate ≤12 mm, and moderate/severe > 12 mm.

The cranial vault asymmetry index (CVAI) is the measure in millimeters at 30° from the center of the nose or the outer edge of the eyebrow. CVAI is calculated in percent from the absolute difference between the two measurements from the left and right side, 30° from the center of the nose, then divided by the greater of the two 30° measurements. A CVAI of Symmetry less than 3.5% is considered within normal limits (level 1), 3.5 to 6.25% is considered minimal (level 2), 6.25 to 8.75 is considered moderate (level 3), 8.75 and 11.0% is considered moderately severe (level 4), and a CVAI that is greater than 11.0% is considered severe (level 5).

Plagiocephaly can be divided into synostotic and non-synostotic types.

I. Synostotic plagiocephaly is an asymmetrically shaped head due to premature closure of the sutures of the cranium.

II. In plagiocephaly without synostosis, the sutures remain open. 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.

III. Brachycephaly results from bilateral coronal synostosis. The cranium is shortened in length and increased in both width and height, or the cranium is elongated and narrow. Mild, transient brachycephaly can also occur as a positional deformity without sutural synostosis in normal babies who are placed in the "back to sleep" position to minimize the risk of sudden infant death syndrome. This form is also especially common in babies who suffer from hypotonia in infancy.

Conservative treatment (e.g., repositioning therapy) should be trialed for a minimum of two months, for children under six (6) months of age. Conservative treatment may consist of any or all of a course of parent/caregiver education, a home exercise program, or physical therapy. The home exercise program incorporates repositioning techniques, which includes reducing the amount of awake time the infants spend on their back, supervised tummy-time, and periodically changing the location of the crib in the nursery. In the first four months of life, conservative treatment may reverse early skull repositioning, but as the infant ages and begins to move independently, the repositioning techniques may become less effective.

RATIONALE

The U.S. Food and Drug Administration (FDA) has cleared for marketing through the 510(k) process multiple cranial orthotic devices including, but not limited to, the Advanced OrthoPro Inc. (AOI) Cranial Helmet, CamLab Cranial Helmet, Cranial Solutions Orthosis, and OttoBock Cranial Helmet, for the indications of moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic and scaphocephalic shaped heads. The FDA summary of evidence for these devices include craniosynostosis and hydrocephalus as contraindications for the cranial orthotic helmet/band.

The primary beneficial outcome of orthotic treatment for positional plagiocephaly is aesthetic improvement of the shape of the head. There have been no studies that have assessed and compared with a well-matched control group, the neurocognitive development of school-aged children with untreated non-synostotic plagiocephaly. Cranial orthotics used to treat non-synostotic (positional) plagiocephaly in cases other than where the axis of the skull has been rotated have not been demonstrated to improve patient outcomes, as its primary beneficial outcome is aesthetic. None of the reviewed trials have randomization, with entry into the helmet arm being guided by clinical opinion or other factors.

In 2011, the American Academy of Pediatrics (AAP) published a revision of its 2003 policy on the prevention and management of positional skull deformities in infants. The AAP indicated that, in most cases, the diagnosis and successful management of deformational plagiocephaly can be assumed by the pediatrician or primary health care clinician and that mechanical methods, if performed early in life, may be effective in preventing further skull deformity and may reverse existing deformity. In most cases an improvement is seen over a two to three-month period with repositioning and neck exercises, especially if these measures are instituted as soon as the condition is recognized. The use of helmets and other related devices seems to be beneficial primarily when there has been a lack of response to mechanical adjustments and exercises, and the best response to helmets occurs in the age range of four to 12 months of age.

The 2005 policy statement from the AAP task force on sudden infant death syndrome stated that consideration should be given to early referral of infants with plagiocephaly when it is evident that conservative measures have been ineffective, as orthotic devices may help avoid the need for surgery in some cases. In 2022, the AAP updated a policy statement entitled “SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment.” In the policy statement, the AAP recommended placing infants on their backs for sleep, with supervised awake “tummy time” for the prevention of plagiocephaly. The policy refers readers to its 2011 clinical report on the prevention and management of positional deformities in infants, which stated that “skull-molding helmets are an option for patients with severe deformity or skull shape that is refractory to therapeutic physical adjustments and position changes”.

Treatment with a cranial orthosis is recommended by Congress of Neurological Surgeons (CNS) evidence-based guidelines regarding cranial molding orthosis for positional plagiocephaly (Tamber MS, et al.) for moderate to severe plagiocephaly that persists after a course of conservative treatment including repositioning and/or physical therapy (strength of recommendations: Level II).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
No specific code(s)	

HCPCS Codes

Code	Description
L0112	Cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
L0113	Cranial cervical orthosis, torticollis type, with or without joint, with or without soft interface material, prefabricated, includes fitting and adjustment
S1040	Cranial remolding orthotic, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

ICD10 Codes

Code	Description
Q67.0-Q67.4	Congenital musculoskeletal deformities of head, face, spine, and chest (code range)

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*Key article

KEY WORDS

Adjustable banding, DOC™, Dynamic Orthotic Cranioplasty, Helmet.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, cranial orthotics is not addressed in National or Regional Medicare coverage determinations or policies.