

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	CRANIAL ORTHOTICS
Policy Number	1.01.32
Category	Equipment/Supplies
Effective Date	10/18/01
Revised 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
Product Disclaimer	<ul style="list-style-type: none"> • 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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

POLICY STATEMENT

- I. Based upon our criteria and the assessment of peer-reviewed literature, cranial orthotics (e.g., helmet or cranial remodeling band) are considered **medically appropriate** when used to treat:
 - A. severe (i.e., cranial vault asymmetry greater than 12mm or cranial vault asymmetry index (CVAI) greater than or equal to 8.75%) non-synostotic (positional) plagiocephaly in conditions where the axis of the skull has been rotated; or
 - B. non-synostotic plagiocephaly with torticollis; or
 - C. brachycephaly when the cranial index is less than 76% or greater than 90%;

AND

 - D. after a failed 2 month trial of conservative treatment, including physical therapy.
- II. Cranial orthotics used to treat non-synostotic (positional) plagiocephaly in all other instances have not been demonstrated to improve patient outcomes, as their primary beneficial outcome is aesthetic. Therefore, cranial orthotics for all other indications are considered **not medically necessary**.
- III. Based upon our criteria and the assessment of peer-reviewed literature, cranial orthotics used in the post-surgical treatment of synostotic plagiocephaly improves patient outcomes and are **medically appropriate**.
- IV. Cranial orthotics as the sole treatment of synostotic plagiocephaly have not been medically proven to be effective and are therefore considered **not medically necessary**.
- V. Cranial orthotics (e.g., helmets) used primarily and customarily for convenience or safety, even though they may have some remote medically related use (e.g., head protection during seizures or self-injurious behavior), are **ineligible for coverage**.

Refer to Corporate Medical Policy #1.01.00 regarding Durable Medical Equipment.

Refer to Corporate Medical Policy #1.01.25 regarding Orthotics.

POLICY GUIDELINES

- I. Cranial index (CI) is defined as the ratio of the *width ÷ length x 100*. A CI ranging from 76-90% is considered *normocephalic*.
- II. Preauthorization is contract dependent. Please contact your local Customer (Member/Provider) Service Department to determine contract coverage.
- III. Orthotic rider/coverage is required. Coverage for external prosthetic devices is contract dependent.

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IV. In general, replacement cranial orthotics are **not medically necessary**.

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. Treatment is typically initiated around 5-6 months of age and continues for an average of 4 to 5 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 (aurion) to the anterior prominence of the right most lateral point on the frontozygomatic suture (frontozygomaticus) and then repeated on opposite side. There are three categories of asymmetry depending on the CVA index. The categories are defined as: (1) normal CVA less than 3mm, (2) moderate CVA 3–12mm, and (3) severe CVA greater than 12mm.

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. Symmetry less than 3.5% is considered within normal limits (level 1), 3.5 to 6.25%, minimal (level 2), 6.25 to 8.75, moderate (level 3). Level 4, which is between 8.75 and 11.0% is considered moderately severe for which a cranial orthosis may be considered. Level 5, in which the CVAI is greater than 11.0% is considered severe and treatment with a cranial orthosis is recommended.

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 6 months of age. Conservative treatment may consist of a course of parent/caregiver education, a home exercise program, or physical therapy, or all of these. 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 4 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.

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RATIONALE

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, 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 their 2003 policy on the prevention and management of positional skull deformities in infants. 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 2- to 3-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 4 to 12 months of age.

In the 2005 policy statement from the AAP task force on sudden infant death syndrome, it was 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 2011, AAP issued a policy statement entitled: SIDS and Other Sleep-Related Infant Deaths: Expansion of Recommendations for a Safe Infant Sleeping Environment. Placing infants on their backs for sleep is recommended with supervised “tummy time” for the prevention of plagiocephaly. The policy refers readers to their 2003 clinical report on the prevention and management of positional deformities in infants. The report states that “skull-molding helmets are an option for patients with severe deformity or skull shape that is refractory to therapeutic to physical adjustments and position changes.”

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.*

CPT Codes

Code	Description
No specific code(s)	

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HCPCS Codes

Code	Description
S1040	Cranial remolding orthosis, rigid, with soft interface material, custom fabricated, including 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, DOCTM, Dynamic Orthotic Cranioplasty, Helmet.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Cranial Orthotics.