MEDICAL POLICY

Medical Policy Title	**Cranial Orthotics**
Policy Number	**1.01.32**
Current Effective Date	May 22, 2025
Next Review Date	May 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Cranial orthotics (e.g., helmet or cranial remodeling band) are considered **medically appropriate** when **ALL** the following are met:
   A. Children aged three (3) to 18 months old;
   B. Failed two-month trial of conservative treatment;
   C. When used to treat **ANY** of the following:
      1. 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%);
      2. Non-synostotic (positional) plagiocephaly with torticollis; **or**
      3. Brachycephaly, when the cranial index is less than 76% or greater than 90%.

II. Cranial orthotics used in the post-surgical treatment of craniosynostosis (synostotic plagiocephaly) are considered **medically appropriate.**

III. Cranial orthotics (e.g., helmet or cranial remodeling band) are **contraindicated** in the following situations:
   A. Hydrocephalus;
   B. Craniosynostosis without prior surgical intervention

IV. Cranial orthotics when used to treat non-synostotic (positional) plagiocephaly are considered **not medically necessary** in all other situations as their primary beneficial outcome is aesthetic (e.g., mild non-synostotic plagiocephaly).

V. Cranial orthotics as the sole treatment of synostotic plagiocephaly are considered **not medically necessary.**

VI. Replacement cranial orthotics are considered **not medically necessary.**

RELATED POLICIES

Corporate Medical Policy

1.01.00 Durable Medical Equipment

1.01.25 Orthotics

POLICY GUIDELINE(S)

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).

IV. A request for a second orthotic will be reviewed on a case by case basis and documentation accompanying the request must demonstrate how the child's head has grown so the original orthotic no longer fits after attempted adjustments and the persistent cranial asymmetry must meet the requirements in Policy Statement I.

DESCRIPTION

A cranial orthotic is a device used for non-invasive treatment of non-synostotic or positional plagiocephaly. The goal of a cranial remolding orthosis is to inhibit growth in some areas of an infant's skull and enable growth in others, thus improving cranial asymmetry and/or shape. Orthoses could also prevent infants from lying on the skull's flattened side, thus inhibiting further asymmetric development. Those in use today are designed to apply passive pressure to prominent and/or normal regions of the cranium while allowing space for growth of flattened regions. Cranial orthoses must be adjusted as a patient's head shape changes. Both helmet and band-type designs are made of varying materials and features, including closed or open top trims. The earlier an infant begins treatment, the greater the likelihood of attaining a head shape within normal limits (Larsen 2004).

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.

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 (2) 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.

SUPPORTIVE LITERATURE

Petz AM, et al. (2024) published results from a retrospective study of infants treated for deformational plagiocephaly with a cranial remolding orthosis. This study compared the time to achieve a successful clinical outcome against the total treatment duration for cranial remolding orthosis therapy in infants with deformational plagiocephaly. A total of 300 infants with deformational plagiocephaly who were treated with a cranial remolding orthosis were grouped by corrected age at initiation of treatment and by severity of deformity. A successful outcome was defined as achieving a final cranial vault asymmetry of 5 mm or less. For the 226 infants who achieved a successful outcome, time to successful outcome and treatment duration were compared between the groups. The time to successful outcome depended on severity but not on age at initiation. The median time to successful outcome ranged from 6 weeks to 17.5 weeks, depending on the severity of the deformity. Time to successful outcome was significantly shorter than treatment duration for infants with an initial cranial vault asymmetry of less than 17 mm. The authors concluded the study showed

estimated treatment timelines should be based on the initial severity of the infant's deformity.

Graham T, et al. (2019) published results from a retrospective chart review study that aimed to examine the statistical effect of a patient's initial deformational severity, age of initiation of cranial remolding orthosis (CRO) treatment, presence or absence of torticollis, and presence or absence of prematurity on the outcome of a patient's CRO treatment. The outcome measures of total CRO treatment time and final head shape. Of the 2,423 charts reviewed, 499 patients were found to meet the inclusion criteria and had complete data for analysis. The included subjects spanned a variety of initial treatment ages and severities. All subjects began treatment at a corrected age between 2 and 17 months and had CVAI measurements spanning from 3.1% to 16.1%. All subjects ended treatment at a corrected age between 5 months and 21 months and had final CVAI measurements between 0.1% and 10.1%. The presence of torticollis was shown to have a statistically significant effect on treatment duration but not on final CVAI. The presence of prematurity was not shown to have a statistical effect on treatment duration or final CVAI. The interaction between the presence of torticollis and prematurity was not statistically significant. When evaluating the treatment time needed to complete orthotic treatment, the following factors were found to be significant: initial age, initial CVAI, and the presence of torticollis. Treatment duration was not found to be affected by the presence of prematurity when postpartum age was corrected by the number of weeks of prematurity. When comparing the post-treatment CVAI, the following factors were found to be significant: age and severity at the initiation of treatment. Both torticollis and prematurity were not found to be significant factors in the overall cranial correction achieved through CRO treatment in this data set.

Based on the results of this study, infants who are older, more severe, and/or have torticollis can expect to need longer treatment durations. However, the presence of torticollis does not preclude achieving similar CVAI correction to infants without torticollis when the torticollis is being concurrently treated with the deformational plagiocephaly. The presence of prematurity does not seem to affect treatment outcomes. When evaluating an infant for CRO treatment, practitioners must decide if treatment is likely to have a positive outcome. By understanding how different factors influence treatment outcomes, practitioners can make more informed decisions about which patients may benefit from CRO treatment. The results of this study suggest that infants have better treatment outcomes when they are younger, less severe, and without torticollis.

Larsen J (2004) published a consensus statement for orthotic treatment protocols for plagiocephaly. The objective of the article was to present findings regarding treatment protocols for deformational plagiocephaly based on the current literature and on a comprehensive survey of 17 orthotic practitioners at various centers nationwide. The survey's 19 questions covered treatment duration, wearing schedules, frequency of follow ups, fitting and follow-up adjustments, variables affecting outcomes, and multiple orthoses. Recommendations were noted including using a cranial orthosis is contraindicated for patients with unshunted hydrocephalus and patients with craniosynostosis except in as-yet-undefined adjunctive treatment. The typical length of treatment for plagiocephaly is anywhere from 6 weeks to 6 months. Cranial orthoses are approved for use on infants, aged 3 to 18 months, with moderate to severe deformational plagiocephaly who have not shown improvement after at least 6 to 8 weeks of repositioning therapy (less than 6 months of age). The best results have been observed in infants aged 4 to 12 months as a result of greater malleability of the skull and rapid brain growth during that period. Although starting treatment at 3 months of age is not

contraindicated, the practitioner could experience two challenges. The first is an increased chance that two orthoses will be necessary to achieve optimal results. This is the result of the occipitofrontal circumference being smaller, thus accommodating less growth. The second challenge is an increase in fitting issues resulting from lack of head control. When treating patients 12 months and older, it is important to initially express realistic expectations to caregivers and to discuss the reduced chance of achieving optimal correction, the extended duration of treatment, and the higher probability that patient will try to remove the orthosis. Patients typically wear cranial orthoses 22 to 23 hours a day for 6 weeks to 6 months. Off-time is used for bathing and hygiene.

At the initial fit, adjustments are provided to maintain suspension, eliminate red areas (if any), and provide proper clearances. As the infant grows into the orthosis, the adjustments shift to accommodating growth while still maintaining total contact for passive correction. It is the practitioner's responsibility to adjust the orthosis to the maximum of its limits, thus reducing the probability of requiring a second orthosis. The extent of the correction that can be achieved is dependent on several factors, including the age of child when entering treatment, type of deformity, severity of initial deformity, and compliance of the treatment protocol. In most cases, the parents and clinicians find the corrected head shape acceptable at the end of the first orthosis. A second orthosis is rarely required but could be used in very severe head deformations, unusual circumstances (illness-negated use or if the child has serious health and/or positioning issues), or unusually high expectations of the family. Criteria for determining a second orthosis include:

- Despite every effort, the orthosis becomes ill-fitting or leaves little or no room for new growth;
- If age and severity indicate another orthosis and parents are willing to continue; and
- If prescribed for use as a continued postoperative adjunct or for preventative measures.

PROFESSIONAL GUIDELINE(S)

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).

Congress of Neurological Surgeons (CNS) (Flannery 2016) published guidelines for the management of patients with positional plagiocephaly after systematic reviews of evidence related to four main topics. Key points are as follows:

I. Physical examination is recommended for diagnosis of plagiocephaly with imaging necessary only rarely (Level III).

II. Physical therapy is recommended rather than positioning pillows (which cause a less safe sleeping environment), and more effective than repositioning education based on evidence from 1 Class-1 study.

III. Helmet therapy is recommended for infants with persistent moderate to severe plagiocephaly despite conservative therapy (Level II).

IV. Helmet therapy is recommended for infants presenting at an advanced age with moderate to severe plagiocephaly (Level II).

REGULATORY STATUS

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 those found on the chart below, 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. For more information, refer to: U.S. Food and Drug Administration

Product	510(k) Number	Approval Date
Advanced OrthoPro Inc. (AOI) Cranial Helmet	K103362	04/18/2011
Michigan Cranial Reshaping Orthosis	K090341	01/06/2010
CamLab Cranial Helmet	K081787	01/27/2009
Cranial Solutions Orthosis	K063133	07/02/2007
Orthotic & Prosthetic Lab Inc. Bivalve Cranial Molding Helmet	K063395	12/22/2006
OttoBock Cranial Helmet	K041215	09/09/2004

Loma Linda University Medical Center (LLUMC) Cranial Remolding Helmet	K023572	01/13/2003
Fairview Orthopedic Lab Molded Cranial Helmet	K012920	11/28/2001
Lerman & Son Cranial Orthosis Helmet	K012830	11/20/2001
Children's Hospital Cranial Helmet (Minneapolis, MN)	K013458	10/29/2001
Ballert Cranial Molding Helmet	K011433	06/12/2001

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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 and face (code range)
Q75.001 - Q75.08	Craniosynostosis [surgically corrected] (code range)

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SEARCH TERMS

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

10/18/01, 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, 12/10/20, 12/16/21, 12/22/22, 12/21/23, 04/18/24, 05/22/25	
Date	**Summary of Changes**
05/22/25	• Annual review, revision to Policy Guidelines, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date