
Medical Policy



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***Current Policy Effective Date: 5/1/22**
(See policy history boxes for previous effective dates)

Title: Cranial Orthosis (Helmet or Band Therapy) as a Treatment of Plagiocephaly

Description/Background

Cranial orthoses involve 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. A cranial orthotic device may be used for the treatment of postsurgical synostosis or positional plagiocephaly in pediatric patients.

Plagiocephaly refers to an asymmetrical shape of the head from repeated pressure to the same area. Plagiocephaly is a common occurrence in infants and may be caused by a variety of factors.

CRANIOSYNOSTOSES

An asymmetrically shaped head due to premature closure of the sutures of the cranium. Functional deficits may result secondary to increasing intracranial pressure in an abnormally or asymmetrically shaped cranium. The type and degree depend on the type of synostosis. The most common is scaphocephaly, a narrowed and elongated head resulting from synostosis of the sagittal suture, while premature fusion of the metopic suture results in a triangular shape of the forehead known as trigonocephaly. Unilateral synostosis of the coronal suture results in an asymmetric distortion of the forehead called plagiocephaly, and fusion of both coronal sutures results in brachycephaly. Combinations of these deformities may also occur.

Treatment

Synostotic deformities associated with functional deficits are addressed by surgical remodeling of the cranial vault. The remodeling (reshaping) is accomplished by opening and expanding the abnormally fused bone.

In a review of the treatment of craniosynostosis, Persing (2008) indicated that premature fusion of one or more cranial vault sutures occurs in approximately 1 in 2500 births.(1) Of these

craniosynostoses, asymmetric deformities involving the cranial vault and base (eg, unilateral coronal synostosis) will have a higher rate of postoperative deformity, which would require additional surgical treatment. Persing suggested that use of cranial orthoses postoperatively may serve two functions: (1) they protect the brain in areas of large bony defects, and (2) they may remodel the asymmetries in skull shape, particularly when the bone segments are more mobile.

PLAGIOCEPHALY

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. Positional plagiocephaly typically consists of right or left occipital flattening with advancement of the ipsilateral ear and ipsilateral frontal bone protrusion, resulting in visible facial asymmetry. Occipital flattening may be self-perpetuating in that once it occurs, it may be increasingly difficult for the infant to turn and sleep on the other side. Bottle feeding, a low proportion of “tummy time” while awake, multiple gestations, and slow achievement of motor milestones may contribute to positional plagiocephaly. The incidence of plagiocephaly has increased rapidly in recent years; this is believed to be a result of the “Back to Sleep” campaign recommended by the American Academy of Pediatrics, in which a supine sleeping position is recommended to reduce the risk of sudden infant death syndrome. It is hoped that increasing awareness of identified risk factors and early implementation of good practices will reduce the development of deformational plagiocephaly.

Treatment

It is estimated that about 2/3 of plagiocephaly cases may auto-correct spontaneously after regular changes in sleeping position or following physical therapy aimed at correcting neck muscle imbalance. A cranial orthotic device is usually requested after a trial of repositioning fails to correct the asymmetry, or if the child is too immobile for repositioning.

The back-sleeping position, recommended in 1992 by the American Academy of Pediatrics to reduce sudden infant death syndrome (SIDS), has been associated with increased frequency of positional plagiocephaly due to pressure on the back of the infant’s head against a firm mattress. Plagiocephaly can most often be diagnosed on physical exam. However, x-ray or CT scan may be needed to exclude conditions requiring surgical intervention.

Cranial orthotic devices have been designed to treat plagiocephaly without synostosis or deformational plagiocephaly and include both soft-shell helmets and cranial headbands.

The device applies pressure to prominent regions of an infant’s cranium in order to improve cranial symmetry and/or shape. The FDA classified the cranial orthosis as a class II device, which requires a prescription.

The three types of molding helmets that can be used are:

- For positional plagiocephaly, either a(n):
 - Passive helmet or
 - Active helmet
- For rigid fixation, a postoperative/molding helmet is used to maintain the shape of the remolded calvarium and protect the brain until the skull is healed solidly.

Regulatory Status

Multiple cranial orthoses (helmets) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process are intended to apply passive pressure to prominent regions of an infant's cranium to improve cranial symmetry and/or shape in infants from 3 to 18 months of age. Multiple marketed devices are labeled for use in children with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic- and brachycephalic-shaped heads. FDA product code: MVA.

Medical Policy Statement

The safety and effectiveness of cranial orthoses (helmets) have been established as a treatment of plagiocephaly. Cranial orthoses may be considered a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:

A custom cranial orthosis may be a therapeutic option if **all** of the following conditions are met:

- For synostotic plagiocephaly or non-synostotic plagiocephaly, the cranial orthosis must be an FDA-approved device intended for the treatment of deformational plagiocephaly (including plagiocephalic, brachycephalic and scaphocephalic shaped heads) in order to provide a reasonable assurance of safety and effectiveness **AND**
- Following corrective surgery for synostotic plagiocephaly **OR**
- The infant is from age 3-18 months with persistent non-synostotic plagiocephaly who has failed conservative treatment, (i.e., positional changes)

Note: Cranial orthoses require multiple fittings as the infant's skull grows to make room for the brain.

Exclusions:

All other indications not listed in inclusions

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes

S1040

Other codes (investigational, not medically necessary, etc.)

97799

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

CRANIAL ORTHOSES FOR CRANIOSYNOSTOSIS

Clinical Context and Test Purpose

The purpose of postoperative cranial orthosis is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as cranial vault remodeling without a cranial orthosis, in patients with open or endoscopic surgery for craniosynostosis.

The question addressed in this evidence review is: Does the use of an adjustable cranial orthosis improve the net health outcome in infants who have undergone open or endoscopic surgery for craniosynostosis?

The following PICO's were used to select literature to inform this review.

Populations

The relevant population of interest are individuals with open or endoscopic surgery for craniosynostosis.

Interventions

The therapy being considered is postoperative cranial orthosis.

Comparators

Comparators of interest include cranial vault remodeling without a cranial orthosis. Treatments for craniosynostosis include surgeries such as strip sagittal craniectomy, frontal-orbital advancement, and frontal-occipital reversal.

Outcomes

The general outcomes of interest are a change in disease status, morbid events, functional outcomes, QOL, and treatment related morbidity. The existing literature evaluating postoperative cranial orthosis as a treatment for open or endoscopic surgery for craniosynostosis has varying lengths of follow-up, ranging from 13 to 25 months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 12 to 24 months of follow-up is considered appropriate to demonstrate efficacy. Patients with open or endoscopic surgery for craniosynostosis are actively managed by neurosurgeons, plastic surgeons, and primary care providers in an inpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Early literature consisted of a few case series that described the use of cranial orthoses following either open or endoscopically assisted surgery for craniosynostosis. For example, Kaufman et al (2004) reported on 12 children, who used a cranial orthosis for one year after extended strip craniectomy.(3) They found that the orthoses improved Cephalic Index score (100 times the ratio of cranial biparietal diameter and occipitofrontal diameter) more than a similar type of surgery without an orthosis reported elsewhere. The Cephalic Index score improved by four (range, 67-71) from baseline to one year in studies using surgery alone but improved by 10 (range, 65-75) with combined treatment (Cephalic Index normal range, 75-90). Stevens et al (2007) reported on a study that evaluated 22 patients from a single institution, on the effect of postoperative remolding orthoses following total cranial vault remodeling.(4) The children's ages at the time of surgery ranged from 4 to 16 months (average age, 7.5 months). For the 15 (68%) of 22 children treated who completed helmet use and were not lost to follow-up, helmets were worn an average of 134 days. Summary Analyses were not provided because each patient case differed by location of fused suture, extent and duration of the fusion, and surgical methods used.

Jimenez et al (2002, 2007, 2012) reported on routine use of helmets for 12 months following endoscopically assisted surgery for craniosynostosis in 256 consecutive children.(5-7) Anthropomorphic measurements at 3, 6, 9, and 12 months after surgery showed continued improvement in symmetry in most patients. Jimenez and Barone (2010) reported treatment of 21 infants with multiple-suture (non-syndromic) craniosynostosis with endoscopically assisted craniectomies and postoperative cranial orthoses.(8) Helmet therapy lasted an average of 11 months (range, 10-12 months). The decision to discontinue therapy was based on the child reaching the 12-month postoperative mark or 18 months of age. After the first-year post surgery, patients were followed annually or biannually (range, 3-135 months). The mean preoperative Cephalic Index score was 98. The postoperative Cephalic Index score (>1 year) was 83, a 15% decrease from baseline.

Since these initial reports, literature updates have identified larger series describing endoscopically assisted strip craniectomy and postoperative helmet therapy for craniosynostosis. They include a series of 97 children with non-syndromic single-suture synostosis reported by Gociman et al (2012) and a series of 73 children reported by Honeycutt (2014).(9,10) Honeycutt asserted that because head-shape correction occurs slowly after surgery, helmet therapy is as important as the surgery to remove the abnormal suture.

Shah et al (2011) prospectively collected outcomes from endoscopically assisted vs open repair of sagittal craniosynostosis in 89 children treated between 2003 and 2010.(11) The endoscopic procedure was offered starting in 2006 and has become the most commonly performed approach. The 42 patients treated with open-vault reconstruction had a mean age at surgery of 6.8 months and a mean follow-up of 25 months. Mean age of the 47 endoscopically treated patients at surgery of 3.6 months and a mean follow-up was 13 months. Of the 29 endoscopically treated patients who completed helmet therapy, the mean duration for helmet therapy was 8.7 months. Noncompliance with helmet therapy has also been reported in a substantial proportion of patients.(12)

Section Summary: Cranial Orthoses for Craniosynostosis

The evidence on the efficacy of cranial orthoses following endoscopically assisted or open cranial vault remodeling surgery for craniosynostosis is limited and includes only case series. In the postoperative period after craniosynostosis repair, the role of cranial orthoses is to continue remodeling the skull after surgery. Functional impairments are related to craniosynostosis, including the potential for increased intracranial pressure and risk of harm from additional surgery when severe deformity has not been corrected. This indirect evidence is considered sufficient to suggest an improvement in health outcomes with postsurgical use of cranial orthosis for craniosynostosis.

CRANIAL ORTHOSES FOR POSITIONAL PLAGIOCEPHALY

The management of positional deformity is controversial, and treatment recommendations and outcomes reporting are variable.

Jung et al (2020) discuss positional plagiocephaly in infants and the controversy surrounding the age at which helmet therapy should be initiated and how long treatment should be maintained.(13) Change of position and observation are often the main method of treatment when positional plagiocephaly is discovered in the early stages. There are three reasons for the controversy regarding the age at which helmet treatment should be initiated. First, the degree of asymmetry of the head determines the feasibility of helmet treatment. Therefore, variation in the results according to the degree of asymmetry will be apparent, regardless of the timing of the helmet treatment. Second, most patients who receive helmet treatment also receive conservative treatment, such as changing the posture, which limits the accurate determination of the effect of helmet treatment. Third, the duration of treatment and pressure exerted by the helmet vary according to the physicians and the type of helmet used. When to initiate helmet therapy based on age has proven most challenging. Better results have been reported, by most studies, when helmet therapy is initiated earlier rather than later. The reported average of helmet therapy is between two to six months. Experts agreed that helmet treatment should be instituted before infants are able to control their head movements, although the minimum age of eligibility was not defined. Approximately 85% of cranial growth is achieved in the first 12 months after birth, and the cranial growth rate is significantly decreased from 12 months until 24 months of age. If positional plagiocephaly has not responded to conservative treatment doctors recommend that treatment should be initiated before six months of age, during the early stage of development, when the skull is rapidly growing. Helmet therapy was found to be very effective when initiated before 12 months of age. Therapy that has been initiated after 12 months of age was found to be less effective and therapy that is initiated after 18 months of age was found to have very poor results. Authors concluded that for the patients with positional plagiocephaly, appropriate helmet therapy can be a very effective treatment to change the shape and position of the head when initiated in accordance with cranial growth spurts.

Wen et al (2020) evaluated a total of 376 infants, age 2-40 months, who were diagnosed with mild-moderate-severe positional head deformity.(14) Among these infants, 101 infants were treated with helmet therapy or postural correction training. After matching by infant's age and time of therapy, three retrospective cohort studies of 56 infants were conducted for infants with plagiocephaly, brachycephaly and asymmetrical brachycephaly, respectively. The cephalic ratio (CR), radial symmetry index (RSI), cranial vault asymmetry (CVA) and cranial vault asymmetry index (CVAI) were compared between two groups before and after treatment.

Before treatment, no significant differences in CR, RSI, CVA and CVAI between groups were found. After treatment, compared with the postural correction training group, the helmet therapy group had significant improvements in CR, RSI, CVA or CVAI (Plagiocephaly: $P_{CVA} = 0.017$, $P_{CVAI} = 0.028$; Brachycephaly: $P_{CR} = 0.002$; Asymmetrical brachycephaly: $P_{RSI} = 0.002$, $P_{CVA} < 0.001$, $P_{CVAI} < 0.001$). Moreover, there was no significant difference in head circumference growth between the groups. The authors concluded that helmet therapy may be more effective in the treatment of mild-moderate-severe positional head deformity than postural correction training in infants; And helmet therapy may not hinder head circumference growth.

Lam et al (2017) reviewed an institutional experience (2008-2014) with the treatment of positional plagiocephaly in 991 infants less than 1 year old; Factors associated with measured improvement were explored.(15) The most common deformity was occipital plagiocephaly (69.5%), followed by occipital brachycephaly (18.4%) or a combination of both deformities (12.1%). The recommended treatment(s) were geared according to an age- and risk factor-dependent algorithm and included repositioning (RP), physical therapy (PT) if indicated, or orthotic treatment with a customized cranial orthosis (CO). Of the 991 eligible patients, 884 returned for at least 1 follow-up appointment. A total of 552 patients were followed to completion of their treatment and had a full set of records for analysis: these patients had pre- and post-treatment 2D surface scanner evaluations. The average presenting age was 6.2 months (corrected for prematurity for treatment considerations). Of the 991 patients, 543 (54.8%) had RP or PT as first recommended treatment. Of these 543 patients, 137 (25.2%) transitioned to helmet therapy after the condition did not improve over 4-8 weeks. In the remaining cases, RP/PT had already failed before the patients were seen in this program, and the starting treatment recommendation was CO. At the end of treatment, the measured improvements in oblique diagonal difference (ODD) were 36.7%, 33.5%, and 15.1% for patients receiving CO, RP/PT/CO, and RP/PT, respectively. Univariate analysis showed that sex, race, insurance, diagnosis, sleep position preference, torticollis history, and multiple gestation were not significantly associated with magnitude of ODD change during treatment. On multivariate analysis, corrected age at presentation and type of treatment received were significantly associated with magnitude of ODD change. Orthotic treatment corresponded with the largest ODD change, while the RP/PT group had the least change in ODD. Earlier age at presentation corresponded with larger ODD change.

Shamij et al (2012) surveyed parents of 80 children treated for positional plagiocephaly to assess cosmetic outcome, school performance, language skills, cognitive development, and societal function.(16) Analysis indicated that the children of respondents were representative of the total pool. Positional therapy was applied in all children, while 36% also used helmet therapy. At a median follow-up of 9 years, normal head appearance was reported in 75% of cases. Compared with right-sided deformation, left-sided plagiocephaly was associated with a need for special education classes (27% vs 10%), fine motor delay (41% vs 22%), and speech delay (36% vs 16%).

Section Summary: Cranial Orthoses for Positional Plagiocephaly

Treatment with a custom cranial orthosis can result in better improvements of head shape measurements and functional performance. The degree of measured deformational head shape correction in positional plagiocephaly are impacted by age at presentation and type of treatment.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Table 1. Summary of Key Trials

NCT. No.	Trial Name	Planned Enrollment	Completion Date
NCT02370901 ^a	Cranial Orthotic Device Versus Repositioning Techniques for the Management of Plagiocephaly: the CRANIO Randomized Trial (CRANIO)	226	Nov 2020

^a Denotes industry-sponsored or cosponsored trial
NCT: national clinical trial

SUMMARY OF EVIDENCE

For individuals who have plagiocephaly, relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life and treatment related morbidity. Functional impairments are related to craniosynostosis. Normally the skull accommodates brain growth by uniformly expanding through the suture lines. When normal brain growth is restricted and must be redirected within the finite space, increased intracranial pressure is the effect, resulting in impaired brain development. Cranial orthoses can facilitate remodeling, thus allowing for normal brain expansion. Therefore, the use of a cranial orthosis is likely to improve outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke (2019) states that “Treatment for craniosynostosis generally consists of surgery to improve the symmetry and appearance of the head and to relieve pressure on the brain and the cranial nerves, [although] for some children with less severe problems, cranial molds can reshape the skull to accommodate brain growth and improve the appearance of the head.(21)

American Academy of Pediatrics

The AAP (2011) revised its 2003 policy on the prevention and management of positional skull deformities in infants.(17,18) 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 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 seem 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 a policy statement, the AAP (2011) indicated that consideration should be given to early referral of infants with plagiocephaly when it is evident that conservative measures have been ineffective, because orthotic devices may help avoid the need for surgery in some cases.(19)

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.(17) 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.”

Congress of Neurological Surgeons

There is a fairly substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial shape in infants with positional plagiocephaly treated with a helmet as compared to conservative therapy, especially if the deformity is severe, and provided that helmet therapy is applied during the appropriate period of infancy. Specific criteria regarding the measurement and quantification of deformity and the most appropriate time window in infancy for treatment of positional plagiocephaly with a helmet remain elusive. In general, infants with a more severe presenting deformity and infants who are helmeted early in infancy tend to have more significant correction (and even normalization) of head shape.(20)

Government Regulations

National

No National Coverage Determination noted.

Local

No Local Coverage Determination noted.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 11/30/21, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/25/02	3/25/02	3/25/02	Joint policy established
9/9/03	9/9/03	10/3/03	Routine maintenance; procedure code update
11/8/04	11/8/04	12/2/04	Routine maintenance
12/30/05	12/30/05	1/23/06	Routine maintenance
5/1/07	2/15/07	2/15/07	Routine maintenance
5/1/08	2/19/08	5/1/08	Routine maintenance
5/1/09	2/10/09	2/10/09	Routine maintenance
7/1/12	4/10/12	5/18/12	Routine maintenance
1/1/14	10/17/13	10/25/13	Routine maintenance
5/1/15	2/17/15	2/27/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance
7/1/18	4/17/18	4/17/18	Routine maintenance
7/1/19	4/16/19		Routine maintenance
5/1/20	2/18/20		Routine maintenance
5/1/21	2/16/21		Routine maintenance
5/1/22	2/15/22		Routine maintenance

Next Review Date: 1st Qtr, 2023

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 10/25/00	Revised: N /A
BCBSM: 4/30/00	Revised: N/A

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CRANIAL ORTHOSIS (HELMET OR BAND THERAPY)
AS A TREATMENT OF PLAGIOCEPHALY**

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.