Medical Policy

BlueCross BlueShield of Kansas
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Title: Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses

Professional
Original Effective Date: July 13, 2004
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Populations	Interventions	Comparators	Outcomes
Individuals: • Who have open or endoscopic surgery for craniosynostosis	Interventions of interest are: • Postoperative cranial orthosis	Comparators of interest are: • Endoscopic or open cranial vault remodeling without a cranial orthosis	Relevant outcomes include: • Change in disease status • Morbid events • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With positional plagiocephaly	Interventions of interest are: • Cranial orthosis	Comparators of interest are: • Positioning therapy	Relevant outcomes include: • Change in disease status • Morbid events • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

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 positional plagiocephaly or postsurgical synostosis in pediatric patients.

OBJECTIVE

The objective of this policy is to determine whether the use of an adjustable cranial orthosis improves the net health outcome in infants who have undergone open or endoscopic surgery for craniosynostosis or who have positional plagiocephaly.

BACKGROUND

Craniosynostoses

An asymmetrically shaped head may be synostotic or nonsynostotic. Synostosis, defined as 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. The most common is scaphocephaly, a narrowed and elongated head resulting from synostosis of the sagittal suture. Trigonocephaly, in contrast, is premature fusion of the metopic suture and results in a triangular shape of the forehead. 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 2008 review of the treatment of craniosynostosis, Persing 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 2 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 has been suggested 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 two-thirds 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.

REGULATORY STATUS

A number of devices 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. FDA product code: MVA.

POLICY

A. Use of an adjustable cranial orthosis may be considered **medically necessary** following cranial vault remodeling surgery for synostosis.

B. Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered **not medically necessary.**

C. Use of an adjustable cranial orthosis as a treatment of plagiocephaly or brachycephaly without synostosis is considered **not medically necessary.**

Policy Guidelines

1. Procedures are considered medically necessary if there is a significant physical functional impairment AND the procedure can be reasonably expected to improve the physical functional impairment, ie, improve health outcomes.
2. Assessment of plagiocephaly in research studies may be based on anthropomorphic measures of the head, using anatomical and bony landmarks. However, there is no accepted minimum objective level of asymmetry for a plagiocephaly diagnosis.

RATIONALE

The most recent literature update was performed through January 8, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

This review was informed by a TEC Assessment (1999) that concluded the evidence on adjustable cranial orthoses as a treatment of positional plagiocephaly was insufficient to permit conclusions.[2]

Cranial Orthoses for Craniosynostosis

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 1 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 4 (range, 67-71) from baseline to 1 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 on treatment of

21 infants with multiple-suture (nonsyndromic) 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 postsurgery, 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 nonsyndromic 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 was 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

Results from a pragmatic multicenter, single-blinded, randomized controlled trial (HEADS [HElmet therapy Assessment in Deformed Skulls]) were reported in 2014.[13] The trial included 84 infants ages 5 to 6 months with moderate-to-severe skull deformation (oblique diameter difference index ≥108% or craniproportional index ≥95%) who were randomized to cranial orthoses for 6 months or to the natural course (observation). It should be noted that 3% of infants recruited were excluded from the trial due to very severe deformation (oblique diameter difference index >113% or craniproportional index >104%). Of the 42 infants randomized to a cranial orthosis, 10 (23%) wore a cranial orthosis until 12 months of age. Parents of 10 infants discontinued treatment before 12 months due to adverse events. The primary outcome (change score for plagiocephaly [oblique diameter difference index] and brachycephaly [craniproportional index] at 24 months) was similar for the 2 groups. Full recovery was reported for 26% of children in the

orthoses group and 23% of children in the observation arm (odds ratio, 1.2; 95% confidence interval, 0.4 to 3.3; p=0.74).

A systematic review by McGarry et al (2008) described 9 publications involving the use of cranial orthoses.[14] More than half of the studies were retrospective cohorts; none was randomized. For studies comparing orthoses with active counter positioning, one reported greater decreases in posterior cranial asymmetry (from 12 to 0.6 mm) than treatment of infants using repositioning alone (from 12 to 10 mm); other studies found faster, but ultimately similar, reductions in asymmetry with helmets.[15,16] Another 2008 systematic review identified 7 cohort studies meeting selection criteria.[17] In most studies, physicians offered (and parents elected) the method of treatment, resulting in a bias toward older infants and greater deformity in the molding groups. One study (2005) included 159 infants with molding therapy and 176 treated with repositioning and physical therapy.[18] Molding therapy was recommended for infants older than 6 months with more severe deformity, and repositioning was recommended for infants 4 months or younger. Both treatments were offered for infants between 4 and 6 months of age, although anthropomorphic measurements indicated that molding therapy was effective in 93% of infants, while repositioning was effective in 79% of infants. In this review, the relative risk was 1.3 favoring molding therapy. A prospective longitudinal study by Kluba et al (2014) evaluated 128 infants treated with or without a helmet; authors found that, although children treated with a helmet had more severe asymmetry originally, they showed significantly more improvement (68% vs 31%).[19] In a study of 1050 infants, Couture et al (2013) reported on the successful use of off-the-shelf helmet therapy.[20] Infants with an Argenta classification type I (minimal deformity) were treated with repositioning while infants with an Argenta severity rating of II to V were treated with a helmet. Correction (overall rate, 81.6%) took longer in patients with an Argenta severity of III, IV, and V compared with Argenta type II, but was not significantly affected by age.

Positional Plagiocephaly and Functional Outcomes

Since publication of the TEC Assessment (1999), few studies have examined the association between positional plagiocephaly and functional impairments. Some, such as that by Fowler et al (2008), found no difference in the neurologic profile, posture, or behavior of 49 infants with positional plagiocephaly compared with 50 age-matched concurrent controls.[21]

Other studies have compared developmental outcomes in children using positional plagiocephaly with normative values. Panchal et al (2001) reported that scores from a standardized measure of mental and psychomotor development differed significantly from the expected standardized distribution, with 8.7% of children categorized as severely delayed on the Mental Development Index compared with the expected 2.5%.[22] A study by Miller and Clarren (2000) obtained responses on long-term developmental outcomes in 63 of 181 children asked to participate in this study.[23] Results were limited by the lack of concurrent controls and potential self-selection population bias. In addition, these studies did not evaluate the possible causal relation for the observed association. For example, children with preexisting development delays or weakness might be at a higher risk for plagiocephaly if they were more apt to lie in 1 position for extended periods of time.

The effect of treatment for positional plagiocephaly on health outcomes has also been investigated. For example, 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.[24] 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
Results from the HEADS trial have suggested that, in a practice setting, the effectiveness of a cranial orthoses may not differ from the natural course of development for infants with moderate to severe plagiocephaly and brachycephaly. However, the validity of these results is limited by the low percentage of infants who wore the cranial orthoses for the duration of the trial and the relatively low percentage of infants who achieved recovery in either group. In addition, the efficacy of cranial orthoses in infants with very severe plagiocephaly was not addressed. A few reports have assessed the association between positional plagiocephaly and functional impairments. The largest controlled study found no difference in function between infants with plagiocephaly and age-matched concurrent controls. While some series have suggested an association between plagiocephaly and developmental delay, they lacked controls and did not evaluate the possible causal relation to observed association. Results of a study on right-sided vs left-sided plagiocephaly suggested an association between left-sided and functional performance, but these results would need corroboration.

SUMMARY OF EVIDENCE

For individuals who have open or endoscopic surgery for craniosynostosis who receive a postoperative cranial orthosis, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Overall, the evidence on the efficacy of cranial orthoses following endoscopic-assisted or open cranial vault remodeling surgery for craniosynostosis is limited. However, functional impairments are related to craniosynostosis, and there is a risk of harm from additional surgery when severe deformity has not been corrected. Because cranial orthoses can facilitate remodeling, use of a cranial orthosis is likely to improve outcomes after cranial vault remodeling for synostosis. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have positional plagiocephaly who receive a cranial orthosis, the evidence includes a comparative study and case series. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Overall, evidence on an association between positional plagiocephaly and health outcomes is limited. The largest controlled study found no difference in function between infants with plagiocephaly and age-matched concurrent controls. Taking into consideration the limited number of publications over the past decade and the likelihood of both study and publication bias in uncontrolled studies, the scientific literature does not support an effect of deformational plagiocephaly on functional health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

CLINICAL INPUT RECEIVED THROUGH PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 physician specialty societies (4 reviews) and 2 academic medical centers while this policy was under review in 2008. Input was mixed about whether the use of helmets/adjustable banding for treatment of plagiocephaly or brachycephaly without synostosis should be considered medically necessary or not medically necessary. Clinical input agreed that cranial orthoses may be indicated following cranial vault surgery.

PRACTICE GUIDELINES AND POSITION STATEMENTS

Congress of Neurological Surgeons et al

In 2016, the Congress of Neurological Surgeons, American Association of Neurological Surgeons, the Congress of Neurological Surgeons, and American Academy of Pediatrics published a joint evidence-based guideline on the role of cranial molding orthosis therapy for patients with positional plagiocephaly.[25,26] They provided level II recommendations (uncertain clinical certainty) on the use of helmet therapy "for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy)" and "for infants with moderate to severe plagiocephaly presenting at an advanced age." The recommendations were based on a randomized controlled trial, 5 prospective comparative studies, and 9 retrospective comparative studies (all rated as class II evidence).

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke has stated 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."[27]

National Health Service Quality Improvement

In 2007, Scotland's National Health Service Quality Improvement issued an evidence note on the use of cranial orthosis treatment for infant deformational plagiocephaly.[28] No evidence-based conclusions could be reached due to the limited methodologic quality of available trials.

American Academy of Pediatrics

In 2011, the American Academy of Pediatrics (AAP) revised its 2003 policy on the prevention and management of positional skull deformities in infants.[29,30] 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 prevent 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. AAP indicated that use of helmets and 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 a 2011 policy statement, AAP 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.[31] AAP also recommended placing infants on their backs for sleep with supervised "tummy time" for the prevention of plagiocephaly.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

97799	Unlisted physical medicine/rehabilitation service or procedure
S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment

ICD-10 Diagnoses

M95.2	Other acquired deformity of head
M99.80	Other biomechanical lesions of head region
Q67.2	Dolichocephaly
Q67.3	Plagiocephaly
Q67.4	Other congenital deformities of skull, face and jaw
Q75.0	Craniosynostosis
Q75.1	Craniofacial dysostosis
Q75.8	Other specified congenital malformations of skull and face bones
Q75.9	Congenital malformation of skull and face bones, unspecified

REVISIONS

10-11-2011	Policy added to the bcbsks.com web site.
09-05-2013	Updated Description.
	In the Policy section:

	▪ Revised Item B from: " An adjustable cranial orthosis as a treatment of moderate to severe plagiocephaly without synostosis is considered medically necessary when all the following criteria are met: 1. The infant is at least 3 months of age but not greater than 18 months of age; AND 2. Marked asymmetry has not been substantially improved following conservative therapy of at least 2 months duration with cranial repositioning therapy. Due to the mobility of infants greater than 4 months of age, repositioning therapy is not effective and thus, a trial of repositioning is not indicated; AND 3. Asymmetry of the cranial base as documented by any of the following: a. *Skull Base Asymmetry*: At least 6 mm right / left discrepancy measure subnasally to the tip of the tragus (cartilaginous projection of the auricle at the front of the ear); or b. *Cranial Vault Asymmetry*: At least a 8 mm right / left discrepancy, measured from the frontozygomaticus point (identified by palpation of the suture line above the upper outer corner of the orbit) to the contralateral euryon, defined as the most lateral point on the head located in the parietal region; or c. *Asymmetry of the orbitotragial distances*, as documented by at least 4 mm right / left asymmetry measure from the lateral aspect of orbit to tip of ipsilateral tragus. 4. The custom molded orthotic is designed to fit a child's head from 2-4 months. A second helmet or band may be required if the asymmetry has not resolved or significantly improved after 2-4 months." ▪ Revised Item C from: "Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery and as treatment of brachycephaly is considered medically necessary."
	Updated Rationale section.
	In Coding section: ▪ Added ICD-10 Diagnosis codes. *(Effective October 1, 2014)*
	Updated Reference section.
07-08-2015	Updated Rationale section.
	Updated References section.
01-04-2017	Updated Description section.
	In Policy section: ▪ In Item C, added "Use of" to read, "Use of an adjustable cranial orthosis as a treatment of plagiocephaly or brachycephaly without synostosis is considered not medically necessary." ▪ In Policy Guidelines Item 2, removed "The following table presents normative values and the mean pretreatment asymmetries reported in large case series. These may be useful in determining if a significant variation from normal is present." and Table 1. ▪ Removed Policy Guidelines Item 3.
	Updated Rationale section.
	Updated References section.
09-28-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
01-01-2018	In Coding section: ▪ Deleted CPT code: 97762. ▪ Removed ICD-9 codes.
04-11-2018	Updated Description section.

	Updated Rationale section.
	Updated References section.

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