

1.01.11	Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses		
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Section:	1.0 Durable Medical Equipment	Page:	Page 1 of 15

Policy Statement

Use of an adjustable cranial orthosis may be considered **medically necessary** for **either** of the following indications:

- Post cranial vault remodeling surgery for synostosis (craniosynostosis surgery)
- Moderate to severe non-synostotic plagiocephaly or brachycephaly when **all** of the following criteria are met:
 - Patient is at least three months but not greater than 18 months of age
 - Documented trial of conservative treatment (e.g., cranial repositioning therapy or physical therapy) of at least two months or a statement indicating why repositioning is not practical (See Policy Guidelines)
 - Documentation of cranial asymmetry by **one or more** of the following cephalometric anthropomorphic measurements (See Policy Guidelines):
 - Skull base asymmetry greater than or equal to 6 millimeters (mm)
 - Cranial vault asymmetry greater than or equal to 6 mm
 - Orbitotragial depth asymmetry greater than or equal to 6 mm
 - A cephalic index/ratio two standard deviations above or below the mean for gender and age (most common measurement for brachycephaly)

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

(See below for discussion of use of an adjustable cranial orthosis as a reconstructive service.)

Policy Guidelines

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 (i.e., improve health outcomes). In this policy, procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease, or congenital defect. Not all benefit contracts include benefits for reconstructive services as defined herein.

Assessment of plagiocephaly in research studies may be based on anthropomorphic measures of the head, using anatomic and bony landmarks. However, there is no accepted minimum objective level of asymmetry for a plagiocephaly diagnosis. Table 1 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.

Table 1. Pretreatment Asymmetries Reported in Large Case Series

Study	Cranial Base, mm	Cranial Vault, mm	Orbitotragial Distance, mm
Moss (1997) ³²	NR	9.2	7.1 ^a
Littlefield et al (1998) ³³	6.17	8.50	4.36
Teichgraeber et al (2002) ³⁴	7.08	8.53	3.12

NR: not reported.

^a In this report, the asymmetry was measured from the tragus to the frontozygomatic point instead of the exocanthion.

The cranial remodeling orthosis (HCPCS codes **S1040**, **L0112**, and **L0113**) includes the cost of consultations, scans, casting, fitting, assessment, and adjustment visits until the desired measurements are achieved.

Note: Cranial remodeling orthosis or cranial helmets, when used primarily for convenience or safety, are not considered durable medical equipment and are ineligible for coverage.

Conservative therapy may include:

- Repositioning of the infant's head to the opposite of the infant's preferred position when either lying down, reclined, or sitting
- Performing infant neck exercises at each diaper change
- Repositioning the infant's bed encouraging the infant to look away from the flattened side to view individuals in the room
- Physical therapy or occupational therapy

Note: Due to the mobility of infants greater than four to six months of age; a trial of repositioning may not be practical.

Anthropomorphic Assessment of Plagiocephaly

Cranial Base

Asymmetry of the cranial base is measured from the subnasal point (midline under the nose) to the tragus (the cartilaginous projection in front of the external auditory canal).

Cranial Vault

Asymmetry is assessed by measuring from the frontozygomaticus point (identified by palpation of the suture line above the upper outer corner of the orbit) to the euryon, defined as the most lateral point on the head located in the parietal region.

Orbitotragial Depth

Asymmetry of the orbitotragial depth is measured from the exocanthion (outer corner of the eye fissure where the eyelids meet) to the tragus (the cartilaginous projection in front of the external auditory canal)

Cranial Index

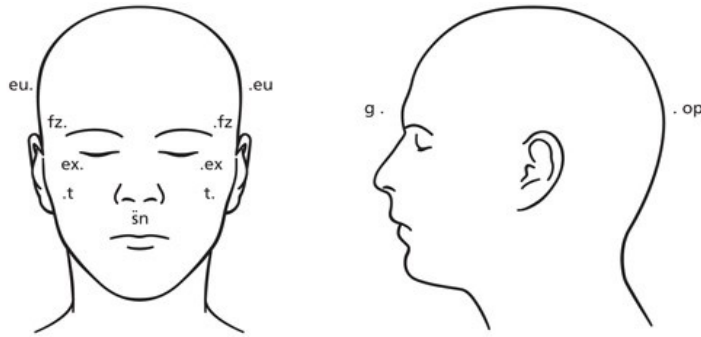
The cranial index, which describes a ratio of the maximum width to the head length expressed as a percentage, is used to assess abnormal head shapes without asymmetry. The maximum width is measured between the most lateral points of the head located in the parietal region (i.e., euryon). The head length is measured from the most prominent point in the median sagittal plane between the supraorbital ridges (i.e., glabella) to the most prominent posterior point of the occiput (i.e., the opisthocranium), expressed as a percentage. The cranial index can then be compared to normative measures.

Anthropometric Measurements

Moderate to severe plagiocephaly or brachycephaly is verified by anthropometric data (measurements used to evaluate abnormal head shape by measuring the distance in millimeters from one-predesignated point on the face or skull to another, comparing the right and left sides).

Measurements are normally obtained by a physician, technician, or orthotist experienced in cephalometric anthropomorphic measurement and fitting of the band or helmet.

Diagram:



The primary areas measured and asymmetry (a discrepancy of 6 to 12 millimeters) is calculated, as shown in the following table:

Craniofacial Area	Measurement	Determines Asymmetry	Calculated
Cranial (skull) base	From right and left subnasal (<u>sn</u>) point (midline under the nose) to tragus (<u>t</u>) (cartilaginous projection of the auricle at the front of the ear)	Upper jaw depth or right and left face height	<u>sn</u> to left t minus <u>sn</u> to right t
Cranial vault	From frontozygomatic point (<u>fz</u>) point (forehead just above the eye orbit) to right and left euryon (<u>eu</u>) (most lateral point of the head)	Bones of the skull enclosing the brain	left <u>fz</u> to right <u>eu</u> minus right <u>fz</u> to left <u>eu</u>
Orbitotragial depth or distances	From right and left exocanthion (<u>ex</u>) point (outer point of the eye where the eyelids meet) to tragus (<u>t</u>)	Cheek bones below the eyes	left <u>ex</u> to left t minus right <u>ex</u> to right t

Cephalic Index

Cephalic index = $\frac{\text{Head width (eu to eu)}}{\text{Head length (g to op)}} \times 100$

Head length (g to op)

Head width (eu to eu)	From euryon (<u>eu</u>) on one side of head to euryon (<u>eu</u>) on the other side	Measures greatest transverse diameter or maximal head width
Head length (g to op)	From glabella (<u>g</u>) point to opisthocranium (<u>op</u>)	Measures maximal head depth or length

Standard Deviation (SD) Table for Cephalic Index (Farkas & Munro, 1987):

Sex	Age	-2 SD	-1 SD	Mean	+1 SD	+2 SD
Male	16 days to six months	63.7	68.7	73.7	78.7	83.7
	six to 12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days to six months	63.9	68.6	73.3	78.0	82.7
	six to 12 months	69.5	74.0	78.5	83.0	87.5

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 to treat postsurgical synostosis or positional plagiocephaly in pediatric patients.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Several devices cleared for marketing by the U.S. Food and Drug Administration 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. Food and Drug Administration product code: MVA.

Rationale

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. Trigenocephaly, 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 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 (e.g., 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, two domains are examined: the relevance, and 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

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 PICOs were used to select literature to inform this review.

Patients

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:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- d. Studies with duplicative or overlapping populations were excluded.

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.^{5,6,7} 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 the 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 a 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 (2014) 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 the 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

Clinical Context and Test Purpose

The purpose of cranial orthosis is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as positioning therapy, in patients with positional plagiocephaly.

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 positional plagiocephaly?

The following PICOs were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with positional plagiocephaly. Some increase in the prevalence of positional plagiocephaly may be related to the change in recommended sleep practice (back to sleep) to prevent sudden infant death syndrome.

Interventions

The therapy being considered is cranial orthosis. Custom-fitted cranial orthoses are designed to be worn 23 hours a day for several months.

Comparators

Comparators of interest include positioning therapy. Treatment for positional plagiocephaly includes head repositioning and helmet therapy. 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.

Outcomes

The general outcomes of interest are a change in disease status, morbid events, functional outcomes, QOL, and treatment-related morbidity. Guideline-related systematic reviews reported a mean duration of cranial orthotic as four-six months depending on the age of the patient with longer-term outcome assessments reported at two years. Patients with positional plagiocephaly are managed by neurologists, pediatricians and other primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- d. Studies with duplicative or overlapping populations were excluded.

Positional Plagiocephaly and Anthropometric Outcomes

Results from a pragmatic multicenter, single-blinded, randomized controlled trial, 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 $\geq 108\%$ or cranioproportional index $\geq 95\%$) 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 cranioproportional 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 [cranioproportional 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 six months with more severe deformity, and repositioning was recommended for infants four 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 the 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 one 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 the 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, a 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 HEImet therapy Assessment in Deformed Skulls trial have suggested that, in a practice setting, the effectiveness of 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 have not been confirmed. During the 2019 update for this policy, professional society clinical input was sought with a response that acknowledged the evidence limitations but an endorsement of current professional guidelines.

Summary of Evidence

For individuals who have open or endoscopic surgery for craniosynostosis who receive a postoperative cranial orthosis, the evidence includes case series. The relevant outcomes are a change in disease status, morbid events, functional outcomes, QOL, 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. The relevant outcomes are a change in disease status, morbid events, functional outcomes, QOL, 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 low likelihood of development of high-level evidence from controlled studies, the scientific literature is limited in support of an effect of deformational plagiocephaly on functional health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes. However, during the 2019 update for this policy, professional society clinical input was sought with a response that acknowledged the evidence limitations but an endorsement of current professional guidelines.

Supplemental Information

Clinical Input From 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 from Blue Cross Blue Shield Association, input was received from 3 physician specialty societies (4 reviews) and 2 academic medical centers in 2008. Input was mixed about whether the use of helmets or adjustable banding for treatment of plagiocephaly or brachycephaly without synostosis should be considered medically necessary or not medically necessary. Input agreed that cranial orthoses may be indicated following cranial vault surgery.

Practice Guidelines and Position Statements

Congress of Neurological Surgeons and Section on Pediatric Neurosurgery

The Congress of Neurological Surgeons and the Section on Pediatric

Neurosurgery(2016) published a joint evidence-based guideline on the role of cranial molding orthosis therapy for patients with positional plagiocephaly.^{25,26} The guideline was endorsed by the Joint Guidelines Committee of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons and American Academy of Pediatrics (AAP).

The guideline 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, five prospective comparative studies, and nine retrospective comparative studies (all rated as class II evidence).

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke (2017) 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

Scotland's National Health Service Quality Improvement (2007) 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

The AAP (2011) revised its 2003 policy on the prevention and management of positional skull deformities in infants.^{29,30} 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 prevent further skull deformity and may reverse existing deformity. In most cases, 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 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 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.³¹ The 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.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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 ^a	Cranial Orthotic Device Versus Repositioning Techniques for the Management of Plagiocephaly: the CRANIO Randomized Trial	226	Nov 2020

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

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Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including: past treatments (start and duration) and progress, proposed treatment plan
- Anthropometric cranial measurements documenting asymmetry (e.g., skull base, cranial vault, orbitotragial distances/depth, cephalic index)

Post Service

- Results/reports of tests performed

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/NMN

The following services may be considered medically necessary when policy criteria are met. Services may be considered not medically necessary when policy criteria are not met.

Type	Code	Description
CPT®	97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
	97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
	97799	Unlisted physical medicine/rehabilitation service or procedure
HCPCS	L0112	Cranial cervical orthotic, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
	L0113	Cranial cervical orthotic, 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)
ICD-10 Procedure	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
06/09/1999	Policy Name Change Policy Adopted and Approved for Certain Indications.	Medical Policy Committee MPCQT
12/07/2006	Policy Name Change Policy revised- BCBSA MPP adopted. Criteria updated. Now considered I/E	Medical Policy Committee
01/11/2008	Policy Name Change Policy revised- Criteria updated. Approved only in limited situations.	Medical Policy Committee
09/12/2008	Policy Revision -Criteria updated for MN and IE and NMN indications. Literature review and coding update. Policy title change. Prior Policy title: Dynamic Orthotic Cranioplasty for the Treatment of Positional Plagiocephaly	Medical Policy Committee
05/06/2009	Coding Update	Administrative Review
07/17/2009	Administrative Review	Administrative Review
01/20/2010	Administrative Review	Administrative Review
10/07/2011	Policy revision with position change	Medical Policy Committee
07/31/2015	Coding Update Policy title change from Cranial Remodeling Orthosis Policy revision without position change	Medical Policy Committee
12/01/2016	Policy revision without position change	Medical Policy Committee
10/01/2017	Policy revision without position change	Medical Policy Committee
01/01/2018	Coding update	Administrative Review
05/01/2018	Policy revision without position change	Medical Policy Committee

Effective Date	Action	Reason
09/01/2019	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.