1.01.11	Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses		
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Policy Statement

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

II. Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered **investigational**.

III. Use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly without synostosis may be considered **medically necessary** when all of the following conditions have been met:
   A. Documented failure of conservative therapy (repositioning and physical therapy) of at least 2 months duration
   B. The individual has a cephalic index that is at least two standard deviations above or below the mean for the appropriate gender and age
   C. The individual is between 3 and 18 months old

IV. Use of an adjustable cranial orthosis is considered **investigational** for all other indications not outlined above.

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

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

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. Although, there is no accepted minimum objective level of asymmetry for a plagiocephaly diagnosis there are definitions that have been adopted by convention:

- Brachiocephaly: Shortened front to back dimension of the skull that results from premature fusion of the coronal suture
- 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)
- Cephalic index: The cephalic 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 opisthocranion), expressed as a

percentage. The cephalic index can then be compared to normative measures for age and gender. See Table PG1 (as developed by American Academy of Orthotists and Prosthetists 2004). The policy criteria requiring an individual to have a cephalic index of 2 standard deviations above or below the mean for the use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly was based on populations included within the evidence base.

- 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. The cranial vault asymmetry index (CAVI) can be used to assess cranial shape and is calculated by taking the difference between the diagonals of the head (measured from the anthropometric points), dividing by the larger diagonal, and multiplying by 100 to get a percentage. The Children's Healthcare of Atlanta plagiocephaly severity scale, based on clinical presentation and CAVI, was developed in 2017 to assist with clinical treatment recommendations and is shown in Table PG2.[1,]
- Plagiocephaly: Flattening of the skull on the back or one side of the head.
- Sagittal suture: Skull joint that separates the left and right halves of the skull.

Table PG1. Cephalic Index

Sex	Age	-2SD	-1SD	Mean	+1SD	+2SD
Male	16 days to 6 months	63.7	68.7	73.7	78.7	83.7
Male	6 to 12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days to 6 months	63.9	68.6	73.3	78.0	82.7
Female	6 to 12 months	69.5	74.0	78.5	83.0	87.5

SD: standard deviation.

Table PG2. Children's Healthcare of Atlanta Plagiocephaly Severity Scale

Level	Clinical Presentation	Recommendation	CVAI
1	All symmetry within normal limits	No treatment required	<3.5
2	Minimal asymmetry in one posterior quadrant No secondary changes	Repositioning program	3.5 to 6.25
3	Two quadrant involvement Moderate to severe posterior quadrant flattening Minimal ear shift and/or anterior involvement	Conservative treatment: Repositioning Cranial remolding orthosis (based on age and history)	6.25 to 8.75
4	Two or three quadrant involvement Severe posterior quadrant flattening Moderate ear shift Anterior involvement including noticeable orbit asymmetry	Conservative treatment: Cranial remolding orthosis	8.75 to 11
5	Three or four quadrant involvement Severe posterior quadrant flattening Severe ear shift Anterior involvement including orbit and cheek asymmetry	Conservative treatment: Cranial remolding orthosis	> 11

CVAI: Cranial Vault Asymmetry Index.

Coding

See the Codes table for details.

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.

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 a 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 an 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 a 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 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 that the technology results in an improvement in the net health outcome.

Additional Information

2008 Input

Multiple medical organization guidelines have supported use of orthoses for positional plagiocephaly with criteria. The conditions for which the medical organizations noted that use of helmets and related devices seem to be primarily beneficial may, therefore, be considered medically necessary.

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

Multiple cranial orthoses (helmets) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process and 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.

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 increased intracranial pressure in an abnormally or asymmetrically shaped cranium. The type and degree of craniofacial deformity depend 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 a 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 1 or more cranial vault sutures occurs in approximately 1 in 2500 births.[2,] 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 (2008) 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 the 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.

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, 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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 (RCT) 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.

Cranial Orthoses for Craniosynostosis

Clinical Context and Therapy 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 individuals with open or endoscopic surgery for craniosynostosis.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is 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, quality of life, 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 1 outcome of interest, longer follow-up is necessary to fully observe outcomes. Therefore, 12 to 24 months of follow-up is considered appropriate to demonstrate efficacy.

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

Case Series

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] The authors 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 to 71) from baseline to 1 year in studies using surgery alone but improved by 10 (range, 65 to 75) with combined treatment (Cephalic Index normal range, 75 to 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 to 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 to 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 versus 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 Therapy 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 individuals with positional plagiocephaly.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is 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, quality of life, and treatment-related morbidity. Guideline-related systematic reviews reported a mean duration of cranial orthotic as 4 to 6 months depending on the age of the patient with longer-term outcome assessments reported at 2 years.

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
Positional Plagiocephaly and Anthropometric Outcomes
Results from a pragmatic, multicenter, single-blind, RCT (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=.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, 1 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

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 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 HElmet 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 versus 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, although the evidence limitations were acknowledged, given that multiple medical organization guidelines have supported use of orthoses for positional plagiocephaly with criteria, use of cranial orthoses were made medically necessary for certain conditions.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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, 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 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

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Congress of Neurological Surgeons and Section on Pediatric Neurosurgery

In 2016, the Congress of Neurological Surgeons and the Section on Pediatric Neurosurgery commissioned a systematic review to inform a joint evidence-based guideline on the role of cranial molding orthosis therapy for patients with positional plagiocephaly.[25,26,] The guideline was issued by a multidisciplinary task force that included clinical and methodological experts; all task force members were required to disclose potential conflicts of interest. 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, 5 prospective comparative studies, and 9 retrospective comparative studies (all rated as class II evidence).

National Institute of Neurological Disorders and Stroke

In 2019, 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,]

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 ongoing 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 (Status)
Ongoing			
NCT06173102	Treatment Effectiveness of Cranial Orthosis Therapy in the Correction of Deformational Plagiocephaly: a Randomized Controlled Pilot Study Comparing Cranial Orthosis Therapy to the Natural Course	24	Oct 2024
NCT05917678	Effectiveness of Repositioning, Physical Therapy, and Cranial Remolding in Infants With Cranial Deformation	65	Jul 2027
NCT06762691	Cranial Remolding Orthosis Registry	500	Apr 2030
Unpublished			
NCT02370901[a]	Cranial Orthotic Device Versus Repositioning Techniques for the Management of Plagiocephaly: the CRANIO Randomized Trial	226	Nov 2022 (last updated Nov 2021)

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

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Documentation for Clinical Review

Please provide the following documentation:

- 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 (in addition to the above, please include the following):

- 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.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	97799	Unlisted physical medicine/rehabilitation service or procedure
HCPCS	S1040	Cranial remolding orthotic, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

Policy History

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

Effective Date	Action
06/09/1999	Policy Name Change Policy Adopted and Approved for Certain Indications.
12/07/2006	Policy Name Change Policy revised- BCBSA MPP adopted. Criteria updated. Now considered I/E
01/11/2008	Policy Name Change Policy revised- Criteria updated. Approved only in limited situations.
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
05/06/2009	Coding Update
07/17/2009	Administrative Review
01/20/2010	Administrative Review
10/07/2011	Policy revision with position change
07/31/2015	Coding Update Policy title change from Cranial Remodeling Orthosis Policy revision without position change
12/01/2016	Policy revision without position change
10/01/2017	Policy revision without position change
01/01/2018	Coding update
05/01/2018	Policy revision without position change
09/01/2019	Policy revision without position change
06/01/2023	Policy reactivated. Previously archived from 04/01/2020 to 05/31/2023.
05/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.

05/01/2025	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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 and Feedback (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 at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses 1.01.11 **Policy Statement:** I. Use of an adjustable cranial orthosis may be considered **medically necessary** following cranial vault remodeling surgery for synostosis. II. Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered **investigational**. III. Use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly without synostosis may be considered **medically necessary** when all of the following conditions have been met: A. Documented failure of conservative therapy (repositioning and physical therapy) of at least 2 months duration B. The individual has a cephalic index that is at least two standard deviations above or below the mean for the appropriate gender and age C. The individual is between 3 and 18 months old IV. Use of an adjustable cranial orthosis is considered **investigational** for all other indications not outlined above. (See below for discussion of use of an adjustable cranial orthosis as a reconstructive service.)	**Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses 1.01.11** **Policy Statement:** I. Use of an adjustable cranial orthosis may be considered **medically necessary** following cranial vault remodeling surgery for synostosis. II. Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered **investigational**. III. Use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly without synostosis may be considered **medically necessary** when all of the following conditions have been met: A. Documented failure of conservative therapy (repositioning and physical therapy) of at least 2 months duration B. The individual has a cephalic index that is at least two standard deviations above or below the mean for the appropriate gender and age C. The individual is between 3 and 18 months old IV. Use of an adjustable cranial orthosis is considered **investigational** for all other indications not outlined above. (See below for discussion of use of an adjustable cranial orthosis as a reconstructive service.)