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Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

EXCEPTION: For HCSC members residing in the state of Arkansas, § 23-79-150 relating to musculoskeletal disorders of the face, neck, or head, requires coverage, when such coverage is elected by the group policyholder, for the medical treatment of musculoskeletal disorders affecting any bone or joint in the face, neck, or head, including temporomandibular joint disorder and craniomandibular disorder. Treatment shall include both surgical and nonsurgical procedures. This coverage shall be provided for medically necessary diagnosis and treatment of these conditions whether they are the result of accident, trauma, congenital defect, developmental defect, or pathology. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

Coverage

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

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

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:

- The individual is between 3 and 18 months old;
- Documented failure of conservative therapy (repositioning and/or physical therapy) of at least 2 months duration; and
- Either one of the following sets of measurements or indications:
    1. Asymmetrical appearance confirmed by a right/left discrepancy of greater than 6 mm in any craniofacial anthropometric measurement; **or**
    2. Brachycephalic or dolichocephalic disproportion (comparison of head length versus head width) confirmed by a cephalic index of 2 standard deviations above mean or 2 standard deviations below mean.

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

NOTE 1: Measurements are usually obtained by the physician or orthotist fitting the helmet or headband.

EXCEPTION: TEXAS CHIP and Medicaid (STAR) contracts only: The following directives are required when reviewing patients under the Texas Children's Health Insurance Program (CHIP) or Medicaid State of Texas Access Reform (STAR) Program:

- CHIP – Cranial remolding orthotics are a non-covered service or benefit.
- Medicaid STAR – Per Texas Medicaid Bulletin Number 240, March/April 2012, page 14, "Cranial remolding orthosis…, is no longer a benefit for the treatment of positional plagiocephaly as position plagiocephaly is considered cosmetic. Cranial remolding orthosis is allowed for synostotic plagiocephaly.

Policy Guidelines

Craniofacial Anthropomorphic Measurement

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 1 (as developed by American Academy of Orthotists and Prosthetists 2004).

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.

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 1: Cephalic Index

Sex	Age	- 2 SD	- 1 SD	Mean	+ 1 SD	+ 2 SD
Male	16 days to 6 months	63.7	68.7	73.7	78.7	83.7
	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
	6 to 12 months	69.5	74.0	78.5	83.0	87.5

SD: Standard deviation.

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 post-surgical synostosis or positional plagiocephaly in pediatric patients.

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 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 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 one or more cranial vault sutures occurs in approximately one 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 post-operative deformity, which would require additional surgical treatment. Persing (2008) suggested that use of cranial orthoses post-operatively may serve two functions:

1. They protect the brain in areas of large bony defects, and
2. They may remodel the asymmetries in skull shape, particularly when the bone segments are more mobile.

Plagiocephaly

Plagiocephaly without synostosis, also called positional or deformational plagiocephaly, can be secondary to various environmental factors including, but not limited to, premature birth, restrictive intrauterine environment, birth trauma, torticollis, cervical anomalies, and sleeping position. Positional plagiocephaly typically consists of right or left occipital flattening with advancement of the ipsilateral ear and ipsilateral frontal bone protrusion, resulting in visible facial asymmetry. Occipital flattening may be self-perpetuating in that once it occurs, it may be increasingly difficult for the infant to turn and sleep on the other side. Bottle feeding, a low proportion of “tummy time” while awake, multiple gestations, and slow achievement of motor milestones may contribute to positional plagiocephaly. The incidence of plagiocephaly has increased rapidly in recent years; this is believed to be a result of the “Back to Sleep” campaign recommended by the American Academy of Pediatrics (AAP), 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.

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

This policy was created in 1996 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through December 19, 2022.

Medical policies assess the clinical evidence to determine whether the use of a 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 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 technology, 2 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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 patients with open or endoscopic surgery for craniosynostosis.

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

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

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 was 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.

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. (2) 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 post-operative remolding orthoses following total cranial vault remodeling. (3) 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. (4-6) 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 post-operative cranial orthoses. (7) 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 post-operative mark or 18 months of age. After the first year post-surgery, patients were followed annually or biannually (range, 3 to 135 months). The mean preoperative Cephalic Index score was 98. The post-operative 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 post-operative 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). (8, 9) 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. (10) 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. (11)

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 post-operative 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

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 patients with positional plagiocephaly.

The question addressed in this medical policy is: Does the use of an adjustable cranial orthosis improve the net health outcome in infants who have positional plagiocephaly?

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

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.

Positional Plagiocephaly and Anthropometric Outcomes

Results from a pragmatic multicenter, single-blind, RCT (HEADS [HElmet therapy Assessment in Deformed Skulls]) were reported in 2014. (12) 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. (13) 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. (14, 15) Another 2008 systematic review identified 7 cohort studies meeting selection criteria. (16) 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. (17) 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% versus 31%). (18) In a study of 1050 infants, Couture et al. (2013) reported on the successful use of off-the-shelf helmet therapy. (19) 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. (20)

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%. (21) 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. (22) 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. (23) 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% versus 10%), fine motor delay (41% versus 22%), and speech delay (36% versus 16%).

Section Summary: Cranial Orthoses for Positional Plagiocephaly

Results from the HElmet therapy Assessment in Deformed Skulls (HEADS) 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. Although there are evidence limitations, multiple medical organization guidelines conditionally support the use of orthoses for positional plagiocephaly.

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.

Practice Guidelines and Position Statements

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. (24, 25) 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 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." (26)

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date (Status)
Ongoing			
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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97799
HCPCS Codes	S1040

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
06/15/2024	Reviewed. No changes.
12/01/2023	Document updated with literature review. The following editorial change was made to Coverage: “patients” was changed to “individuals”. No new references added; some removed.
01/01/2023	Document updated with literature review. Coverage unchanged. No new references added; some updated and others removed.
05/15/2021	Reviewed. No changes.
03/01/2020	Document updated with literature review. The following changes were made to Coverage: 1) Added “or” to the following criterion “Documented failure of conservative therapy (repositioning and/or physical therapy) of at least 2 months duration; and”; and 2) Modified measurement criterion to include both craniofacial anthropometric measurement cephalic index measurement.
11/15/2019	Document updated with literature review. The following changes were made to Coverage: 1) Revised conditional criteria for use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly without

	synostosis; 2) Removed section on required documentation for non-surgical requests; 3) Added “Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered not medically necessary.”; and 4) Added “Use of an adjustable cranial orthosis is considered not medically necessary for all other indications not outlined above.”. No new references added. Title changed from “Cranial Remodeling Orthoses (CRO)”.
08/15/2018	Document updated with literature review. Coverage unchanged. References 13-28, and 30 added; numerous references removed.
04/15/2017	Reviewed. No changes.
08/01/2016	Document updated with literature review. Coverage unchanged.
02/01/2015	Reviewed. No changes.
10/15/2013	Literature reviewed. No changes. Title changed from Cranial Remolding Orthosis (CRO) Device.
07/01/2008	Revised/updated entire document
05/01/2007	Coverage revised (photographic evidence requirement removed).
07/01/2005	Revised/updated entire document
08/15/2003	Revised/updated entire document
09/01/1999	Revised/updated entire document
06/01/1999	Revised/updated entire document
05/01/1996	Revised/updated entire document
01/01/1996	New medical document