



Kansas City

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Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses

Policy Number: 1.01.11
Origination: 3/1999

Last Review: 11/2013
Next Review: 11/2014

Policy

In the absence of a benefit exclusion, Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for adjustable cranial orthoses when it is determined to be medically necessary because the criteria shown below are met.

Note: Review benefits for possible exclusions for cranial (head) remodeling band.

When Policy Topic is covered

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

When Policy Topic is not covered

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

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

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

Considerations

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 document, 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 by this document.

Assessment of plagiocephaly in research studies may be based on anthropomorphic measures of the head, using anatomical and bony landmarks. However, there is no accepted minimum objective level of asymmetry for a plagiocephaly diagnosis. The following table presents normative values and the mean pretreatment asymmetries reported in large case series. These may be useful in determining if a significant variation from normal is present.

Study	Cranial Base (mm)	Cranial Vault (mm)	Orbitotragial Distance (mm)
Moss (1)	NR	9.2	7.1*
Littlefield et al. (2)	6.17	8.50	4.36
Teichgraeber et al. (3)	7.08	8.53	3.12

*In this report, the asymmetry was measured from the tragus to the frontozygomatic point instead of the excanthion

Description of Procedure or Service

Cranial orthoses are usually in the shape of 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 requested for the treatment of positional plagiocephaly or postsurgical synostosis in pediatric patients.

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, which describes a narrowed and elongated head resulting from synostosis of the sagittal suture, while premature fusion of the metopic suture results in a triangular shape of the forehead known as trigonocephaly. Unilateral synostosis of the coronal suture results in an asymmetric distortion of the forehead termed plagiocephaly, and fusion of both coronal sutures results in brachycephaly. Combinations of these may also occur. 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.

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 (SIDS). It is hoped that increasing awareness of identified risk factors and early implementation of good practices will reduce the development of deformational plagiocephaly. It is estimated that about two-thirds of cases may correct spontaneously after regular changes in sleeping position or following physiotherapy 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 mobile for repositioning.

Rationale

This policy was originally based on a 1999 TEC Assessment that concluded that the evidence regarding adjustable cranial orthoses as a treatment of positional plagiocephaly was insufficient to permit conclusions. (4) Literature updates using the MEDLINE database have since been performed on a periodic basis. The most recent literature update was performed through February 12, 2013. **Cranial Orthoses for Craniosynostosis**

In a 2008 review of the treatment of craniosynostosis, Persing indicated that premature fusion of one or more cranial vault sutures occurs in approximately 1 in 2,500 births. (5) Of these, asymmetric deformities involving the cranial vault and base (e.g., unilateral coronal synostosis) will have a higher rate of postoperative deformity requiring additional surgical treatment. Persing suggests 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 in situations in which the bone segments are more mobile.

Early literature consisted of a small number of case series that described the use of cranial orthoses following either open or endoscopic-assisted surgery for craniosynostosis. For example, Kaufman et al. reported that use of a cranial orthosis for 1 year after extended strip craniectomy (12 children) appeared to improve the cephalic index when compared with other case series that used a similar type

of surgery without an orthosis. (6) The cephalic index improved by 4 (67 to 71) from baseline to 1 year in studies using surgery alone but improved by 10 (65 to 75) with combined treatment. Stevens and colleagues reported the effect of postoperative remodeling orthoses following total cranial vault remodeling from 22 patients treated at a single institution. (7) The children's' ages at the time of the operation ranged from 4 to 16 months, with an average age of approximately 7.5 months. For the 15 children (68% of the 22 treated) who completed helmet use and were not lost to follow-up, helmets were worn an average of 134 days. Photographic documentation and anthropomorphic measurements from before and after use of the orthosis were presented for a subset of the infants.

Jimenez and colleagues reported routine use of helmets for 12 months following endoscopic-assisted surgery for craniosynostosis in 256 consecutive children. (8-10) Anthropomorphic measurements at 3, 6, 9, and 12 months after surgery showed continued improvement in symmetry in most of the patients. In 2010, Jimenez and Barone reported treatment of 21 infants with multiple-suture (nonsyndromic) craniosynostosis with endoscopic-assisted craniectomies and postoperative cranial orthoses. (11) Helmet therapy lasted for an average of 11 months (range, 10 to 12 months). The decision to discontinue therapy was based on the child's reaching the 12-month postoperative mark or 18 months of age. After the first year following surgery, the patients were followed on an annual or biannual basis (range 3 to 135 months). The mean preoperative cephalic index was 98. The postoperative cephalic index (>1 year) was 83, a 15% decrease from baseline. Photographic documentation and anthropomorphic measurements from before surgery and after use of the orthosis were presented for a subset of the infants.

Since these initial reports, literature updates have identified additional large series describing endoscopically-assisted strip craniectomy and postoperative helmet therapy for the treatment of craniosynostosis. In 2013, Gociman et al. reported use of helmets after minimally invasive (endoscopic) strip craniectomy in 97 children with non-syndromic single-suture synostosis. (12) In 2011, Shah et al. compared prospectively collected outcomes from endoscopically-assisted versus open repair of sagittal craniosynostosis in 89 children who were treated between 2003 and 2010. (13) The endoscopic procedure was offered starting in 2006 and has since transitioned to be 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. The 47 endoscopically treated patients had a mean age at surgery of 3.6 months and a mean follow-up of 13 months. Out of the 29 endoscopically treated patients who completed helmet therapy, the mean duration for helmet therapy was 8.7 months. (Seven patients were not compliant and helmet therapy is ongoing in 11 patients.) The endoscopic procedure with helmet therapy was found to result in shorter operating time (88 vs. 179 minutes), less blood loss (29 vs. 218 mL), reduced need for transfusions (6.4% vs. 100%), and a shorter hospital stay (1.2 vs. 3.9 days), with cephalic indices similar to those obtained from the open procedure (76% vs. 77%). While these results are supportive of this approach, the authors note that the duration and necessity for postoperative molding helmet therapy requires further investigation. Non-compliance with helmet therapy has also been reported in a substantial proportion of patients. (14)

Di Rocco and colleagues described the management of craniosynostosis in 1,286 children hospitalized between 1985–1989 and 2003–2007 at a tertiary care center in Paris. (15) The majority (approximately 87%) had nonsyndromic synostosis. Syndromic craniosynostosis includes Crouzon syndrome, Pfeiffer syndrome, and Apert syndrome. Of the 814 children hospitalized from 2003–2007, 369 presented with sagittal synostosis and 245 of these (66%) were operated on. This retrospective analysis did not describe the management for the remaining 34% (nonsurgically treated group). Also reported in 2009 and 2012 was the development of a normative 3-dimensional database of pediatric craniofacial morphology. (16, 17) The 3-dimensional reconstructions permit comparison of the patient's morphology with normative representations both before and after surgery. Refinement of the software and expansion of the normative database is ongoing.

Cranial Orthoses for Deformational Plagiocephaly

A systematic review published by McGarry et al. in 2008 describes 9 publications involving the use of cranial orthoses. (18) More than half of the studies were retrospective cohorts, and none was

randomized. For the studies that compared orthoses with active counter positioning, 1 reported greater decreases in posterior cranial asymmetry (from 12 mm to 0.6 mm) than treatment of infants using repositioning alone (from 12 mm to 10 mm); another study found faster, but ultimately similar, reductions in asymmetry. (19, 20) Another systematic review from 2008 identified 7 cohort studies meeting the study selection criteria. (21) In the majority of studies, the physicians offered and parents elected the method of treatment, resulting in a bias toward older infants and greater deformity in the molding groups. One of the studies reviewed included 159 infants with molding therapy and 176 treated with repositioning and physiotherapy. (22) 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 4–6 months of age. Anthropomorphic measurements indicated that molding therapy was effective in 93% of infants, while repositioning was found to be effective in 79% of infants. In this study, the risk ratio was about 1.3 favoring molding therapy. These results suggest a very modest improvement in plagiocephaly in comparison with repositioning.

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. Fowler et al. found no difference in the neurologic profile (40 vs. 42 for controls), posture, or behavior of 49 infants (between 4 and 13 months) with deformational plagiocephaly compared with 50 age-matched concurrent controls. (23) Balan and colleagues examined auditory event-related potentials in 10 infants with deformational plagiocephaly compared to 15 sex- and age-matched controls. (24) The infants with plagiocephaly exhibited smaller amplitudes in response. This study did not indicate whether the participants had used therapy. A 2000 study by Miller and Clarren examined long-term development outcomes in 181 children with positional plagiocephaly by inviting families to participate in a telephone interview. (25) Of 63 families who agreed to participate in the interview (33% participation rate), 39.7% of the children had received special help in primary school. These results are limited by potential bias from the self-selected population and low participation rate and are also confounded by the use of adjustable banding in about 50% of the children. In 2001, Panchal and colleagues reported the neurodevelopment of 42 consecutive patients with plagiocephaly prior to the initiation of any therapy. (26) The scores from a standardized measure of mental and psychomotor development in infants from 1–42 months of age were found to be significantly different from the expected standardized distribution, with 8.7% of children categorized as severely delayed on the mental development index compared to the expected 2.5%. While these results suggest an association between plagiocephaly and developmental delay, the study is limited by the lack of controls and does not evaluate the causal relationship 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.

In 2012, Shamji et al. reported cosmetic and cognitive outcomes of positional plagiocephaly treatment. (27) In this study, parents of 80 children who had been treated for positional plagiocephaly responded to surveys that assessed cosmetic outcome, school performance, language skills, cognitive development and societal function. Analysis indicated that the children of the 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 9 years, normal head appearance was reported in 75% of cases. Compared to 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%). It could not be determined from the study design whether this difference was due to the underlying disease or to the treatment. In 2003, Gupta and colleagues reported on the ophthalmologic findings in 93 patients with deformational plagiocephaly; 24% had unilateral or bilateral astigmatism compared with 19% prevalence in the normal population. (28) This study did not indicate whether the participants did or did not undergo therapy.

One report from 2008 suggests that referrals for torticollis may be rising along with positional plagiocephaly (both coincident with national recommendations for infants to sleep in the supine position). (29) Retrospective chart review found that 95% of referrals to a tertiary care center with a

primary diagnosis of torticollis (110 of 139 referred infants had adequate records for review) also presented with plagiocephaly or facial asymmetry. Based on clinical evidence of differing etiologies, the authors concluded that 88% of the torticollis cases were secondary to plagiocephaly. The opposite causal association is discussed in a prospective case series from 2009 that assessed head rotation in 202 infants referred for positional plagiocephaly in 2002-2003. (30) At presentation, the mean transcranial difference was 12.5 mm; 97% of infants had a head rotational asymmetry of equal to or greater than 15 degrees. Ninety-two percent of parents recalled that their child had a preferential head position since soon after birth, although only 24% of infants had been previously diagnosed or treated for torticollis. The authors concluded that the major cause of positional plagiocephaly is limited head mobility in early infancy secondary to cervical imbalance.

Overall, evidence on an association between positional plagiocephaly and health outcomes is limited. The largest controlled study found no difference in function between infants with plagiocephaly and age-matched concurrent controls. Taking into consideration the limited number of publications over the past decade and the likelihood of both study and publication bias in uncontrolled studies, the scientific literature does not support an effect of deformational plagiocephaly on functional health outcomes.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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

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

Summary

Overall, evidence on the efficacy of cranial orthoses following cranial vault remodeling surgery for synostotic plagiocephaly is limited. However, given the functional impairments related to craniosynostosis and the risk of harm from additional surgery when severe deformity has not been corrected, use of a cranial orthosis may be considered medically necessary following cranial vault remodeling for synostosis.

Evidence remains insufficient to determine if adjustable cranial orthoses or helmet therapy is more effective than repositioning over the same time period for positional plagiocephaly. More importantly for this policy, these devices have not been shown to improve functional outcomes. Therefore, molding therapy for positional plagiocephaly is considered not medically necessary.

Practice Guidelines and Position Statements

The National Institute of Neurological Disorders and Stroke (NINDS) states that treatment for craniosynostosis generally consists of surgery to improve the symmetry and appearance of the head and to relieve pressure on the brain and the cranial nerves, although for some children with less severe problems, cranial molds can reshape the skull to accommodate brain growth and improve the appearance of the head. (31)

In 2007, Scotland's National Health Service (NHS) Quality Improvement issued an Evidence Note on the use of cranial orthosis treatment for infant deformational plagiocephaly. (32) No evidence-based conclusions could be reached due to the limited methodologic quality of the available trials. The Evidence Note concluded that further research in the form of a randomized, controlled trial is needed to determine the true effectiveness of cranial orthoses.

In 2003, the American Academy of Pediatrics (AAP) issued a policy indicating that improvement in skull shape is usually seen in 2–3 months with exercise and repositioning of the infant. (33) The AAP indicated that the use of skull-molding helmets seems to be beneficial primarily when there has been a lack of response to mechanical adjustments and exercises. However, the AAP noted further studies are needed to identify outcomes with and without the use of mechanical skull-molding helmets.

In 2005, a policy from the AAP task force on sudden infant death syndrome stated that consideration should be given to early referral of infants with plagiocephaly when it is evident that conservative measures have been ineffective, as orthotic devices may help avoid the need for surgery in some cases. (34)

In 2011, the AAP published a clinical report on the prevention and management of positional skull deformities in infants. (35) The report states that management of positional skull deformity involves preventative counseling for parent, mechanical adjustments, and exercises. Skull-molding helmets are an option for patients with severe deformity or skull shape that is refractory to therapeutic physical adjustments and position changes; there is currently no evidence that molding helmets work any better than positioning for infants with mild or moderate skull deformity. Surgery is rarely necessary but may be indicated in severe refractory cases. There have been no rigorous prospective studies, and there is currently no evidence to suggest that positional skull deformity may cause developmental delays. Similarly, there has been no credible medical evidence to support concerns that positional plagiocephaly is associated with vision development, mandibular asymmetry, otitis media, temporomandibular joint (TMJ) syndrome, scoliosis, or hip dislocation.

Medicare National Coverage

Not applicable

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Billing Coding/Physician Documentation Information

97762	Checkout for orthotic/prosthetic use, established patient, each 15 minutes
97799	Unlisted physical medicine/rehabilitation service or procedure
A8000	Helmet, protective, soft, prefabricated, includes all components and accessories
A8001	Helmet, protective, hard, prefabricated, includes all components and accessories
A8002	Helmet, protective soft, custom fabricated, includes all components and accessories
A8003	Helmet, protective, hard, custom fabricated, includes all components and accessories
A8004	Soft interface for helmet, replacement only
L0112	Cranial cervical orthosis, 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 orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

Additional Policy Key Words

DOC Band
Dynamic Orthotic Cranioplasty

Policy Implementation/Update Information

3/1/99	New policy added to the DME section. Considered not medically necessary.
6/1/00	No policy statement changes.
11/1/00	No policy statement changes.
11/1/01	No policy statement changes. Added statement regarding protective helmets into the considerations section. These are not the same as DOC bands.
11/1/02	Policy statement revised to change surgical treatment of non-synostotic plagiocephaly and post-surgical therapy for synostotic plagiocephaly from not medically necessary to investigational. As groups renew in 2002 this device will be a contract exclusion for most members.
11/1/03	Policy statement revised to include dynamic orthotic cranioplasty or any cranial remodeling devices for any purpose is considered investigational. New coding added.
1/1/05	Policy statement revised, Non-surgical treatment of plagiocephaly changed from investigational to not medically necessary. Added L-codes.
11/1/05	Policy statement revised, non-surgical treatment of brachycephaly without synostosis added as not medically necessary.
11/1/06	No policy statement changes. Removed language regarding protective helmets since it may be confused with adjustable banding. Changed title from <i>Dynamic Orthotic Cranioplasty</i> to <i>Adjustable Banding as a Treatment of Plagiocephaly</i> . Policy statement and other text modified to replace the words "dynamic orthotic cranioplasty" with the term adjustable banding
2/1/07	Coding updates only.
11/1/07	No policy statement changes.
11/1/08	No policy statement changes.
11/1/09	No policy statement changes.
11/1/10	Policy edited for clarity; references reordered; no change in policy statement for nonsynostotic plagiocephaly. Policy statements on craniosynostoses added; considered medically necessary following cranial vault remodeling. Title changed to "Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses"
11/1/11	No policy statement changes.
11/1/12	No policy statement changes.

Appendix

Anthromorphic 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.

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