

Medical Coverage Policy | Cranial Orthoses (Adjustable) for Positional Plagiocephaly and Craniosynostoses



EFFECTIVE DATE: 02/03/2015

POLICY LAST REVIEWED: 08/07/2024

OVERVIEW

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.

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

Medicare Advantage Plans and Commercial

Use of an adjustable cranial orthosis may be considered medically necessary following cranial vault remodeling surgery for synostosis and treatment of persistent plagiocephaly or brachycephaly without synostosis.

Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

For all other indications not outlined above, the use of an adjustable cranial orthosis is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

MEDICAL CRITERIA

Not applicable

BACKGROUND

Craniosynostoses

An asymmetrically shaped head may be synostotic or nonsynostotic. Synostosis, defined as premature closure of the sutures of the cranium, may result in functional deficits secondary to increasing intracranial pressure in an abnormally or asymmetrically shaped cranium. The type and degree of craniofacial deformity depends on the type of synostosis. The most common is scaphocephaly, a narrowed and elongated head resulting from synostosis of the sagittal suture. Trigonocephaly, in contrast, is premature fusion of the metopic suture and results in a triangular shape of the forehead. Unilateral synostosis of the coronal suture results in an asymmetric distortion of the forehead called plagiocephaly, and fusion of both coronal sutures results in brachycephaly. Combinations of these deformities may also occur.

Treatment

Synostotic deformities associated with functional deficits are addressed by surgical remodeling of the cranial vault. The remodeling (reshaping) is accomplished by opening and expanding the abnormally fused bone. In a review of the treatment of craniosynostosis, Persing (2008) indicated that premature fusion of one or more cranial vault sutures occurs in approximately 1 in 2500 births. Of these craniosynostoses, asymmetric deformities involving the cranial vault and base (eg, unilateral coronal synostosis) will have a higher rate of postoperative deformity, which would require additional surgical treatment. Persing suggested that use of cranial orthoses postoperatively may serve 2 functions: (1) they protect the brain in areas of large bony defects, and (2) they may remodel the asymmetries in skull shape, particularly when the bone segments are more mobile.

Plagiocephaly

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

Treatment

It is estimated that about two-thirds of plagiocephaly cases may auto-correct spontaneously after regular changes in sleeping position or following physical therapy aimed at correcting neck muscle imbalance. A cranial orthotic device is usually requested after a trial of repositioning fails to correct the asymmetry, or if the child is too immobile for repositioning.

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, professional society clinical input was sought with a response that acknowledged the evidence limitations but an endorsement of current professional guidelines.

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.

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

For individuals who have positional plagiocephaly who receive a cranial orthosis, the evidence includes a comparative study and case series. Relevant outcomes are 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.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable durable medical equipment benefits/coverage.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS code(s) is medically necessary when filed with a covered diagnosis:

S1040 Cranial remolding orthosis, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s).

Covered ICD-10 Diagnoses

Q67.3

Q75.001-Q75.8

RELATED POLICIES

None

PUBLISHED

Provider Update, October 2024

Provider Update, June 2023

Provider Update, July 2022

Provider Update, December 2021

Provider Update, November 2020

REFERENCES

1. Kaufman BA, Muszynski CA, Matthews A, et al. The circle of sagittal synostosis surgery. *Semin Pediatr Neurol.* Dec 2004; 11(4): 243-8. PMID 15828707
2. Stevens PM, Hollier LH, Stal S. Post-operative use of remoulding orthoses following cranial vault remodelling: a case series. *Prosthet Orthot Int.* Dec 2007; 31(4): 327-41. PMID 18050005
3. Jimenez DF, Barone CM, Cartwright CC, et al. Early management of craniosynostosis using endoscopic-assisted strip craniectomies and cranial orthotic molding therapy. *Pediatrics.* Jul 2002; 110(1 Pt 1): 97-104. PMID 12093953
4. Jimenez DF, Barone CM. Early treatment of anterior calvtimes craniosynostosis using endoscopic-assisted minimally invasive techniques. *Childs Nerv Syst.* Dec 2007; 23(12): 1411-9. PMID 17899128
5. Jimenez DF, Barone CM. Endoscopic technique for sagittal synostosis. *Childs Nerv Syst.* Sep 2012; 28(9): 1333-9. PMID 22872245
6. Jimenez DF, Barone CM. Multiple-suture nonsyndromic craniosynostosis: early and effective management using endoscopic techniques. *J Neurosurg Pediatr.* Mar 2010; 5(3): 223-31. PMID 20192637
7. Gociman B, Marengo J, Ying J, et al. Minimally invasive strip craniectomy for sagittal synostosis. *J Craniofac Surg.* May 2012; 23(3): 825-8. PMID 22565892
8. Honeycutt JH. Endoscopic-assisted craniosynostosis surgery. *Semin Plast Surg.* Aug 2014; 28(3): 144-9. PMID 25210508
9. Shah MN, Kane AA, Petersen JD, et al. Endoscopically assisted versus open repair of sagittal craniosynostosis: the St. Louis Children's Hospital experience. *J Neurosurg Pediatr.* Aug 2011; 8(2): 165-70. PMID 21806358

10. Chan JW, Stewart CL, Stalder MW, et al. Endoscope-assisted versus open repair of craniosynostosis: a comparison of perioperative cost and risk. *J Craniofac Surg*. Jan 2013; 24(1): 170-4. PMID 23348279
11. van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, et al. Helmet therapy in infants with positional skull deformation: randomised controlled trial. *BMJ*. May 01 2014; 348: g2741. PMID 24784879
12. McGarry A, Dixon MT, Greig RJ, et al. Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly. *Dev Med Child Neurol*. Aug 2008; 50(8): 568-76. PMID 18754893
13. Mulliken JB, Vander Woude DL, Hansen M, et al. Analysis of posterior plagiocephaly: deformational versus synostotic. *Plast Reconstr Surg*. Feb 1999; 103(2): 371-80. PMID 9950521
14. Loveday BP, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly?. *J Craniofac Surg*. Jul 2001; 12(4): 308-13. PMID 11482615
15. Xia JJ, Kennedy KA, Teichgraber JF, et al. Nonsurgical treatment of deformational plagiocephaly: a systematic review. *Arch Pediatr Adolesc Med*. Aug 2008; 162(8): 719-27. PMID 18678803
16. Graham JM, Gomez M, Halberg A, et al. Management of deformational plagiocephaly: repositioning versus orthotic therapy. *J Pediatr*. Feb 2005; 146(2): 258-62. PMID 15689920
17. Kluba S, Kraut W, Calgeer B, et al. Treatment of positional plagiocephaly--helmet or no helmet?. *J Craniomaxillofac Surg*. Jul 2014; 42(5): 683-8. PMID 24238984
18. Couture DE, Crantford JC, Somasundaram A, et al. Efficacy of passive helmet therapy for deformational plagiocephaly: report of 1050 cases. *Neurosurg Focus*. Oct 2013; 35(4): E4. PMID 24079783
19. Fowler EA, Becker DB, Pilgram TK, et al. Neurologic findings in infants with deformational plagiocephaly. *J Child Neurol*. Jul 2008; 23(7): 742-7. PMID 18344457
20. Panchal J, Amirshaybani H, Gurwitsch R, et al. Neurodevelopment in children with single-suture craniosynostosis and plagiocephaly without synostosis. *Plast Reconstr Surg*. Nov 2001; 108(6): 1492-8; discussion 1499-500. PMID 11711916
21. Miller RI, Clarren SK. Long-term developmental outcomes in patients with deformational plagiocephaly. *Pediatrics*. Feb 2000; 105(2): E26. PMID 10654986
22. Shamji MF, Fric-Shamji EC, Merchant P, et al. Cosmetic and cognitive outcomes of positional plagiocephaly treatment. *Clin Invest Med*. Oct 06 2012; 35(5): E266. PMID 23043707
23. Tamber MS, Nikas D, Beier A, et al. The Role of Cranial Molding Orthosis (Helmet) Therapy. 2016; <https://www.cns.org/guidelines/browse-guidelines-detail/5-role-of-cranial-molding-orthosis-helmet-therapy>. Accessed January 28, 2021.
24. Tamber MS, Nikas D, Beier A, et al. Guidelines: Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline on the Role of Cranial Molding Orthosis (Helmet) Therapy for Patients With Positional Plagiocephaly. *Neurosurgery*. Nov 2016; 79(5): E632-E633. PMID 27759675
25. National Institute of Neurological Disorders and Stroke (NINDS). Craniosynostosis Information Page. 2017; <https://www.ninds.nih.gov/Disorders/All-Disorders/Craniosynostosis-Information-Page>. Accessed January 11, 2023.
26. Laughlin J, Luerssen TG, Dias MS, et al. Prevention and management of positional skull deformities in infants. *Pediatrics*. Dec 2011; 128(6): 1236-41. PMID 22123884
27. Persing J, James H, Swanson J, et al. Prevention and management of positional skull deformities in infants. American Academy of Pediatrics Committee on Practice and Ambulatory Medicine, Section on Plastic Surgery and Section on Neurological Surgery. *Pediatrics*. Jul 2003; 112(1 Pt 1): 199-202. PMID 12837890
28. AAP Publications Reaffirmed or Retired. *Pediatrics* Jul 2018, 142 (1) e20181297; DOI: 10.1542/peds.2018-1297
29. Moon RY, Moon RY, Darnall RA, et al. SIDS and other sleep-related infant deaths: expansion of recommendations for a safe infant sleeping environment. *Pediatrics*. Nov 2011; 128(5): 1030-9. PMID 22007004

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

