CRANIAL REMOLDING ORTHOSES FOR PLAGIOCEPHALY

Policy Number: 200902-0001
Effective Date: 07/01/2001
Revision Date: 09/30/2009

Overview

Plagiocephaly, which refers to a cranial deformity, can be divided into synostotic and non-synostotic types. Synostotic plagiocephaly, also known as craniosynostosis, is caused by the premature fusion of one or more cranial sutures of the skull, causing the head to grow into an unusual shape. When craniocytosis is suspected, infants are referred to a specialist such as a craniofacial or neurosurgeon. These specialists will order a CT scan or MRI to confirm the diagnosis of craniosynostosis. If a baby has craniosynostosis, surgery is indicated to realign the plates of the skull and allow normal brain and skull growth to occur.

In plagiocephaly without synostosis, the cranial sutures remain open. Plagiocephaly without synostosis, also called positional or deformational plagiocephaly, can be secondary to a variety of factors, including but not limited to premature birth, restrictive intrauterine environment, traumatic birth, torticollis, cervical anomalies, and sleeping position. The incidence of deformational plagiocephaly has increased dramatically since the 1992 American Academy of Pediatrics recommendation that infants sleep on their backs to reduce the incidence of sudden infant death syndrome. There is no conclusive evidence that deformational plagiocephaly is associated with any functional impairment. There is no published data on the outcomes of untreated deformational plagiocephaly. The main reason for treatment is to achieve an acceptable appearance. The natural history of deformational plagiocephaly is undocumented.

Deformational plagiocephaly is diagnosed by clinical examination. Classification of severity is based on cephalic index or anthropomorphic measurements. The infant should be screened for associated conditions, such as congenital muscular torticollis. Congenital muscular torticollis is when the sternocleidomastoid muscle is shortened on one side. Infants with torticollis tilt their head noticeably toward the affected side. Torticollis is present in an estimated 80% of infants with deformational plagiocephaly.[1]

Treatment of deformational plagiocephaly is generally indicated for infants with moderate to severe plagiocephaly. The age at which treatment is begun is the main consideration in determining whether the infant should be initially treated with

[1] When torticollis and plagiocephaly coexist, they could both be the result of limited intrauterine space. Torticollis can also cause plagiocephaly in infants who do not present with plagiocephaly at birth. Treatment for torticollis is usually performed in conjunction with treatment for deformational plagiocephaly. In the majority of cases the first line of treatment for congenital muscular torticollis is repositioning and range of motion and strengthening exercises.

repositioning or molding therapy. Randomized controlled clinical trials would be ideal to address these questions regarding therapeutic efficacy. Unfortunately there are no randomized controlled clinical trials on the treatment of plagiocephaly. Case studies show that consistent repositioning of a sleeping infant's head for a period of 6 to 8 weeks will lead to a favorable outcome in infants less than 6 months of age. In infants 6 to 12 months of age, or when a trial of repositioning fails to correct asymmetry in infants 3 to 6 months of age, a cranial remodeling orthosis is recommended. An important consideration in the use of remolding orthoses is that the efficacy of the orthosis depends heavily on the intrinsic growth capacity of the infant skull. After 12 months of age, cranial growth slows dramatically and an orthosis is not likely to change the shape of the head.

Cranial orthoses are Class II (special controls) devices requiring FDA 510(k) approval. The FDA 510(k) Database can be searched by entering product code OAN or MVA at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Many orthoses in use today are designed to apply passive pressure to prominent regions of the cranium while allowing space for growth of flattened regions. Cranial orthoses are custom made and must be adjusted periodically as the infant's head shape changes. Both helmet and band-type designs are available. Factors that effect correction of deformation include age at initiation of treatment and severity of deformation. To be effective, the orthosis must be worn 22 to 23 hours per day for 3 to 6 months. Parental/caregiver compliance with the treatment program is mandatory for successful outcomes.

Definitions

Cranial remolding orthoses – helmets or headbands which are used for the treatment of deformational plagiocephaly (asymmetrically shaped cranium). Cranial remolding orthoses are custom made using a mold or scan of the infant's head. They are worn for up to 23 hours daily, for 6 to 24 weeks. Regular assessments are required to assess growth and make any necessary adjustments to the orthosis.

Brachcephaly – a head shape that is not asymmetric but is disproportionately short. Infants with deformational brachycephaly have an increased cephalic index due to a very wide and short skull deformity.

Scaphocephaly – a head shape that is not asymmetric but is disproportionately long and narrow. Shape is common in babies who spend extended time in NICU or are side-lying. Infants with deformational scaphocephaly have a lower cephalic index due to a very long and narrow skull deformity.

Policy

Preauthorization by FCHP is required. Preauthorization is not a guarantee of payment. For most plan members, cranial remodeling orthoses are subject to a combined DME/prosthetics and orthotics benefit maximum and/or plan member cost-sharing.

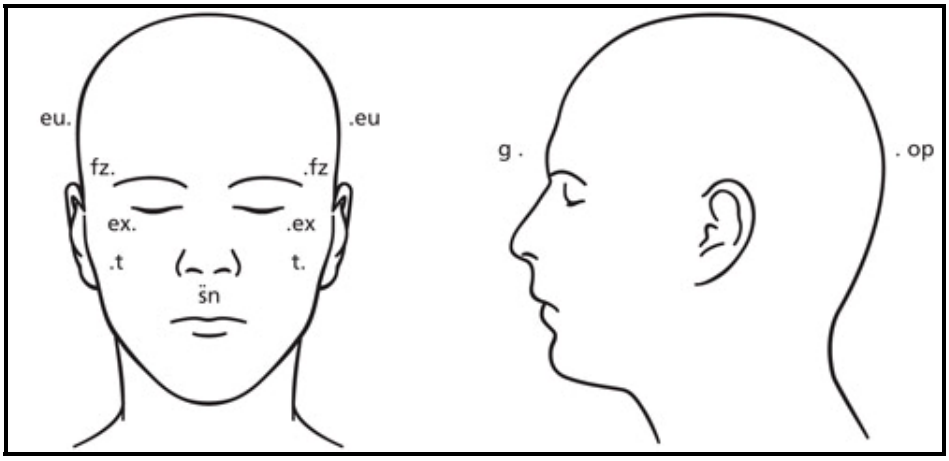
FDA-approved cranial remolding orthoses that have been prescribed by a plan provider are covered for:

1. Infants with moderate to severe (determined by cephalic index or anthropomorphic measurements - see Determination of Severity of Plagiocephaly below) non-synostotic plagiocephaly who meet one of the following criteria:
   a. The infant is 3 to 4 months of age, has been evaluated for the presence of other cranial abnormalities such as craniosynostosis, hydrocephalus and torticollis,[2] and has failed a two-month trial of repositioning to correct cranial deformity.
   b. The infant is 5 to 12 months of age and has been evaluated for the presence of other cranial abnormalities such as craniosynostosis, hydrocephalus and torticollis.
2. Infants 5 to 12 months of age with moderate to severe synostotic plagiocephaly (craniocytosis) that has been surgically repaired.

More than one cranial orthosis is rarely medically necessary because over the course of treatment (typically 3 to 5 months) the orthosis will be modified by the practitioner to provide room for growth.

Determination of Severity of Plagiocephaly

Determination of the severity of plagiocephaly requires precise measurements of the skull using either the cephalic index or anthropomorphic measurements.



Cephalic index

The cephalic index is calculated as follows:

$$\frac{\text{Head width (eu – eu)} \times 100}{\text{Head length (g – op)}}$$

[2] Cranial remodeling orthoses are contraindicated for infants with unshunted hydrocephalus and for infants with craniosynostosis whose synostosis has not been surgically corrected. If non-synostotic plagiocephaly is associated with congenital muscular torticollis, torticollis must be treated in conjunction with treatment for deformational plagiocephaly.

Moderate to severe plagiocephaly is defined as a cephalic index two standard deviations above or below the mean. Infants with deformational scaphocephaly will have a lower cephalic index due to a very long and narrow skull deformity. Infants with deformational brachycephaly will have an increased cephalic index due to a very wide and short skull deformity.

Cephalic Index					
Gender Age	- 2 SD	- 1 SD	Mean	+ 1 SD	+ 2 SD
Male 0 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 0 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

Anthropomorphic measurements

Moderate to severe plagiocephaly is defined as one of the following:

- Cranial base (sn – t): >= 6 mm difference between left and right measurements
- Cranial vault (fz – contralateral eu): >= 8 mm difference between left and right measurements
- Obitotragial depth (ex – t): >= 4 mm difference between left and right measurements

Codes

The cost of a cranial remolding orthosis includes all associated charges, including the initial consultation and evaluation, initial fitting and periodic adjustments. No additional reimbursement is allowed for these services.

Codes	Number	Description
HCPCS	S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fittings and adjustment(s)

Note: HCPCS code L0112 describes a cranial orthosis used for the treatment of congenital muscular torticollis. This policy is not intended to address coverage for cranial orthoses for the treatment of torticollis. HCPCS code L0112 should not be used to bill for cranial remolding orthoses for the treatment of plagiocephaly.

HCPCS codes A8000, A8001, A8002, A8003, and A8004 describe protective helmets. This policy is not intended to address coverage for protective helmets. HCPCS codes A8000, A8001, A8002, A8003, and A8004 should not be used to bill for cranial remolding orthoses for the treatment of plagiocephaly.

Products to Which This Policy Applies

⊕ FCHP Direct & Select Care

⊕ Fallon Preferred Care (PPO)
⊕ Major Medical
∅ MassHealth – refer to MassHealth Guidelines for Medical Necessity Determination for Cranial Orthoses: http://www.mass.gov
∅ Companion Care
∅ Commonwealth Care
∅ Fallon Senior Plan™

References

1. The Office of Health and Human Services. MassHealth Guidelines for Medical Necessity Determination for Cranial Orthoses. Available at: http://www.mass.gov.
2. Fish D and Lima D. An Overview of Positional Plagiocephaly and Cranial Remolding Orthoses. *Journal of Prosthetics and Orthotics* 2003;15(2):37-47.
3. Higuera S, Hollier Jr LH, Stevens PM and Stal S. A Preliminary Investigation of Postoperative Molding to Improve the Result of Cranial Vault Remodeling. *Journal of Prosthetics and Orthotics* 2005;17(4):125-8.
4. Freed SS and Coulter-O'Berry, C. Identification and Treatment of Congenital Muscular Torticollis in Infants. *Journal of Prosthetics and Orthotics* 2004;16(4S):18-23.
5. Larsen J. Orthotic Treatment Protocols for Plagiocephaly. *Journal of Prosthetics and Orthotics* 2004;16(4S):31-4.
6. Littlefield TR. FDA Regulation of Cranial Remodeling Devices. *Journal of Prosthetics and Orthotics* 2004;16(4S):35-8.
7. Steinbok P, Lam D, Singh S et al. Long-Term Outcome of Infants with Positional Occipital Plagiocephaly. *Childs Nerv Syst* 2007 Nov;23(11):1275-83.
8. McGarry A, Dixon MT, Greig RJ et al. Head Shape Standards and Cranial Orthoses in the Tratment of Infants with Deformational Plagiocephaly. *Dev Med Child Neurol.* 2008 Aug;50(8):568-76.
9. Xia JJ, Kennedy KA, Teichgraeber JF et al. Nonsurgical Treatment of Deformational Plagiocephaly: A Systematic Review. *Arch Pediatr Adolesc Med.* 2008 Aug;162(8):719-27.
10. Stellwagen L, Hubbard E, Chambers C, Jones KL. Torticollis, Facial Asymmetry and Plagiocephaly in Normal Newborns. *Arch Dis Child.* 2008 Oct;93(10):827-31.
11. Peitsch WK, Keefer CH, LaBrie RA, Mulliken JB. Incidence of Cranial Asymmetry in Health Newborns. *Pediatrics* 2002 Dec;110(6):e72.
12. Biggs WS. Diagnosis and Management of Positional Head Deformity. *American Family Physician* 2003 Mar;67(9):1953-56.
13. Institute for Clinical Systems Improvement (ICSI). Technology Assessment. Cranial Orthoses for Deformational Plagiocephaly. TA #82. March 2004. ©2004 by ICSI (www.icsi.org).
14. Xiz JJ, Kennedy KA, Teichgraeber JF et al. Nonsurgical Treatment of Deformational Plagiocephaly. *Arch Pediatr Adolesc Med.* 2008;162(8):719-27.
15. Pollack IF, Losken HW, Fasick P. Diagnosis and Management of Posterior Plagiocephaly. *Pediatrics.* 1997 Feb;99(2):180-5.
16. Robinson S, Proctor M. Diagnosis and Management of Deformational Plagiocephaly. *J Neurosurg Pediatr.* 2009 Apr;3(4):284-95.

17. Graham JM Jr, Gomez M, Halberg A, et al. Management of Deformational Plagiocephaly: Repositioning Versus Orthotic Therapy. *J Pediatr.* 2005 Feb;146(2):258-62.
18. AAOS Atlas of Orthoses and Assistive Devices. Fourth Edition. John D. Hsu, John W. Michael, and Jon R. Fisk. Mosby Elsevier, Inc., Philadelphia, PA. ISBN: 978-0-023-03931-4.
19. Teichgraeber FJ, Ault JK, Baumgartner J, et al. Deformational Posterior Plagiocephaly: Diagnosis and Treatment. *Cleft Palate Craniofac J.* 2002;39(6):582-6.
20. Littlefield TR, Beals SP, Manwaring KH, et al. Treatment of Craniofacial Asymmetry with Dynamic Orthotic Cranioplasty. *J Craniofacial Surg.* 1998;9(1):11-17.

Committee review date(s):

Technology Assessment Subcommittee: 03/24/09, 09/22/09
Technology Assessment Committee: 07/01/01, 06/10/2009, 09/30/09