

Cranial Orthotics (cranial bands and helmets)

Date of Origin: 02/2008

Last Review Date: 08/26/2020

Effective Date: 09/01/2020

Dates Reviewed: 02/2009, 02/2011, 01/2012, 10/2012, 08/2013, 08/2015, 08/2016, 08/2017, 08/2018, 08/2019, 08/2020

Developed By: Medical Necessity Criteria Committee

I. Description

Asymmetry of the skull, or plagiocephaly, may be caused by many factors both in-utero or after birth. Plagiocephaly can be classified as positional or non-positional plagiocephaly. Positional plagiocephaly results from external pressure that causes the skull to become misshapen. It is most commonly attributed to positioning in the womb, supine sleeping position, premature birth or prolonged positioning due to a tight sternocleidomastoid muscle. If detected early in infancy, frequent head repositioning and prone positioning during waking hours can correct the deformity for most children. If a conservative approach is unsuccessful, cranial orthotic devices such as soft-shell helmets can be used to mold the infant's skull back into the correct position.

Causes of non-positional plagiocephaly can include synostosis and hydrocephalus. Synostosis, or craniosynostosis, occurs when one or more of the sutures of the infant's skull fuse prematurely. Associated hydrocephalus can occur when two or more have fused. In these situations, treatment includes corrective surgery along with a cranial orthotic device.

II. Criteria: CWQI HCS-0023A

- A. Moda Health will cover cranial orthotics to plan limitations when initiated in patients who are 12 months or younger and **1 or more** the following criteria are met:
 - a. As part of the post-operative treatment plan following surgical correction of synostotic plagiocephaly (asymmetry of the skull), craniosynostosis – (birth defect where one or more suture lines of infant skull closes early), dolichocephalic ({elongated} head shape)
 - b. For the treatment of moderate to severe positional plagiocephaly when **All** of the following conditions are met:
 - i. Failure of a 2-month trial of conservative therapy (repositioning and/or physical therapy) for infants under 6 months of age. For infants 6 months or older, due to increased head control and difficulties in maintaining head position of the infant a trial of repositioning may not be appropriate.

- ii. Anthropometric (skull measurements) data verifies moderate to severe plagiocephaly through a difference of asymmetry greater than 6 mm in **1 or more** of the following measurements:
 1. Skull base
 2. Cranial vault
 3. Orbitotragical depth
- iii. Cephalic index with 2 standards deviations below mean (head is narrow for its length) or 2 standard deviations above mean (head is wide for its length.)

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

- iv. Infants with significant plagiocephaly due to constant head position required for long-term hyperalimentation and who do not respond to simple changing of the catheter position to allow for head repositioning.
 - v. The requested cranial orthotic is NOT for an infant with un-shunted or uncontrolled hydrocephalus
- c. A second cranial remodeling band or helmet is considered medically necessary if the above criteria were met and asymmetry has not resolved after 2 to 4 months of treatment.
- d. Moda Health considers the use of cranial orthotics (bands or helmets) to be experimental and investigational for other indications not listed above. This includes but is not limited to the use in infants with synostotic plagiocephaly (craniosynostosis) who have not had surgical correction.

III. Information Submitted with the Prior Authorization Request:

1. Chart notes from treating physician documenting conservative therapy tried
2. Treatment plan including anthropometric data documented by a provider experienced in these types of measurement (i.e. the orthotist fitting the band or helmet)

IV. CPT or HCPC codes covered:

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

V. Annual Review History

Review Date	Revisions	Effective Date
08/2013	Annual Review: Added table with review date, revisions, and effective date.	08/28/2013
08/2014	Annual Review: No change	08/30/2014
08/2015	Annual Review: Added ICD-9 & ICD-10 codes, definitions of terms and 2 additional HCPC codes, updated references	08/26/2015
08/2016	Annual Review: Deleted ICD-9 codes	08/31/2016
07/2017	Annual Review: Updated to new template, no changes	07/30/2017
08/2018	Annual Review: Added additional references.	08/22/2018
08/2019	Annual Review: No changes	09/01/2019
08/2020	Annual Review: No changes	09/01/2020

VI. References

1. AAP advises on the prevention and treatment of positional plagiocephaly in infants. Hayes Alert. September 1, 2003. Winifred Hayes, Inc. 2003.
2. Caccamese J, Costello BJ, Ruiz RL, Ritter AM. Positional plagiocephaly: evaluation and management. *Oral Maxillofac Surg Clin North Am.* 2004 Nov;16(4):439-46.
3. Doc Band product information. Accessed on February 14, 2011 at: www.cranialtech.com.
4. Freudlsperger C1, Steinmacher S2, Saure D3, Bodem JP2, Kühle R2, Hoffmann J2, Engel M2;
5. Impact of severity and therapy onset on helmet therapy in positional plagiocephaly ; *J Craniomaxillofac Surg.* 2016 Feb;44(2):110-5. doi: 10.1016/j.jcms.2015.11.016. Epub 2015 Dec 8.
6. Fish D, Lima D. An overview of positional plagiocephaly and cranial remolding orthosis. *Journal of Prosthetics and Orthotics* 2003; 15(2):37-50.
7. Govaert B, Michels A, Colla C, Hulst R. Molding therapy of positional plagiocephaly: subjective outcome and quality of life. *J Craniofac Surg.* 2008 Jan;19(1):56-8.
8. Kim HY1, Chung YK1, Kim YO1; Effectiveness of Helmet Cranial Remodeling in Older Infants with Positional Plagiocephaly ; *Arch Craniofac Surg.* 2014 Aug;15(2):47-52. doi: 10.7181/acfs.2014.15.2.47. Epub 2014 Aug 14.

9. Lee A, Van Pelt AE, Kane AA, et al. Comparison of perceptions and treatment practices between neurosurgeons and plastic surgeons for infants with deformational plagiocephaly. *J Neurosurg Pediatr.* 2010 Apr;5(4):368-74.
10. Persing J, James H, Swanson J, et al. Prevention and management of positional skull deformities in infants. *Pediatrics.* 2003 Jul; 112(1):19-202.
11. Pollack IF, Losken HW, Fasick P. Diagnosis and management of posterior plagiocephaly. *Pediatrics.* 1997 Feb;99(2):180-5.
12. Pomatto, Jk, Calcaterra, J., Kelly, DM, Beals, SP, Manwaring, KH, et. al. (2006). A study of family head shape environment alters cranial shape. *Clinical Pediatrics* 2006 Jan-Feb:
13. Stevens PM, Hollier LH, Stal S. Post-operative use of r moulding orthosis following cranial vault remodeling: A case series. *Prosthet Orthot Int.* 2007 Dec;31(4):327-41.
14. Teichgraeber JF, Seymour-Dempsey K, Baumgartner JE, et al. Molding helmet therapy in the treatment of brachycephaly and plagiocephaly. *J Craniofac Surg.* 2004 Jan;15(1):118-23.
15. American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC). Individual Certification. 2014. Available at: <https://www.abcop.org/Pages/default.aspx>.
16. National Commission on Orthotic and Prosthetic Education (NCOPE). Accredited Practitioner Programs. 2014. Available at: <http://www.ncope.org/accredited/practitioner>.
17. van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, et al. Helmet therapy in infants with positional skull deformation: randomised controlled trial. *BMJ.* 2014;348: g2741.
18. Yoo HS1, Rah DK, Kim YO; Outcome analysis of cranial molding therapy in nonsynostotic plagiocephaly; *Arch Plast Surg.* 2012 Jul;39(4):338-44. doi: 10.5999/aps.2012.39.4.338. Epub 2012 Jul 13
19. Physician Advisors

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description
M43.6	Torticollis
M95.2	Other acquired deformity of head
M95.3	Acquired deformity of neck
P13.0	Fracture of skull due to birth injury
Q18.8	Other specified congenital malformations of face and neck
Q67.0	Congenital facial asymmetry
Q67.1	Congenital compression facies
Q67.2	Dolichocephaly
Q67.3	Plagiocephaly
Q67.4	Other congenital deformities of skull, face and jaw
Q68.0	Congenital deformity of sternocleidomastoid muscle
Q75.0	Craniosynostosis
Q75.2	Hypertelorism
Q75.9	Congenital malformation of skull and face bones, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
NA	

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC