

Cranial Orthotics

(Cranial bands and helmets)

Date of Origin: 02/2008

Last Review Date: 07/26/2023

Effective Date: 08/01/2023

Dates Reviewed: 02/2009, 02/2011, 01/2012, 10/2012, 08/2013, 08/2015, 08/2016, 08/2017, 08/2018, 08/2019, 08/2020, 08/2021, 07/2022, 07/2023

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** of 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 – (a birth defect where one or more suture lines of infant skull close 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 the 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. Orbitotriginal depth
- iii. Cephalic index with 2 standard deviations below the mean (head is narrow for its length) or 2 standard deviations above the 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
08/2021	Annual Review: No changes	09/01/2021
07/2022	Annual Review: No changes	08/01/2022
07/2023	Annual Review: No changes	08/01/2023

VI. References

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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