

POLICY – MPP –Cranial Orthotic Devices

Department/Team	Medical Management/Medical Payment Policy (MPP)
Approval By	HQUM
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Line of Business	<input checked="" type="checkbox"/> CCC+ <input checked="" type="checkbox"/> Exchange <input checked="" type="checkbox"/> Medallion 4.0 <input checked="" type="checkbox"/> D-SNP <input type="checkbox"/> MAPD

THIS POLICY HAS BEEN RETIRED 12/27/2021

PURPOSE

This policy outlines guidelines and criteria for coverage determination of cranial orthotic device.

DESCRIPTION

A cranial orthotic device is also referred to as a cranial helmet, cranial orthosis, or cranial band. They are usually custom fit and molded to allow for growth in certain regions of the cranium and concomitant growth restriction in others. Most helmets apply passive restriction rather than active compression forces, encouraging the infant's skull to grow into a desired configuration. In the US, there are currently 37 FDA-approved cranial orthoses listed on the FDA website (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>). Of note, no device has been shown to be superior to another.

There is a lack of evidence from randomized control trials for the use of cranial orthotic devices for the treatment of plagiocephaly. The general consensus is that cranial orthoses are as efficacious, if not more efficacious, in treating deformational plagiocephaly as compared with other more conservative treatments especially for infants with severe plagiocephaly.

The American Academy of Pediatrics (AAP) states that there is no evidence that molding helmets work any better than repositioning therapy for infants with mild to moderate skull deformity (Laughlin, 2011). They recommend repositioning as the initial treatment for infants younger than 6 months. For infants with severe deformity, the AAP states that the use of skull-molding helmets is most effective between the ages of 4-12 months. They indicate that beyond the age of 12 months cranial remodeling is less, and compliance issues increase.

In a 2016 guideline for the treatment of pediatric positional plagiocephaly, the Congress of Neurological Surgeons (CNS) states:

When judging the totality of the evidence, it appears that currently accepted management of positional plagiocephaly in infants—using conservative therapy (repositioning and physical therapy) for the treatment of mild/moderate deformity in younger infants and reserving helmet therapy for more severe deformity,

especially in those older infants who have failed to see improvement with conservative measures—can be justified by the data.

In compliance with federal Early and Periodic Screening, Diagnosis and Treatment (EPSDT) requirements to provide “other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services,” it is acknowledged that cranial orthosis may be considered medically necessary when provided for children with the most severe skull deformities, particularly when coexistent with medical conditions associated with limited mobility. The application of the cranial orthosis does not replace the need for appropriate counter positioning education for caregivers and provision of skilled physical therapy when indicated.

DEFINITIONS

Cosmetic: In this document, procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those which are primarily intended to preserve or improve appearance.

Craniosynostosis – is a congenital deformity of the infant skull that occurs when the fibrous joints between the bones of the skull (called cranial sutures) close prematurely. Due to this closure, the infant develops an abnormally shaped skull because the bones do not expand normally with the growth of the brain.

Medically Necessary: In this document, 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.

Reconstructive: In this 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.

Plagiocephaly: (An asymmetrical head shape) Is most often the result of infant spending extended periods of time on their back, typically during sleep. Plagiocephaly can also occur as a feature of other disorders (e.g., craniofacial disorders, torticollis, and cervical anomalies) and is categorized as either positional or non-positional (premature union of cranial sutures).

Positional Plagiocephaly: Also called deformational plagiocephaly or positional cranial deformity (PCD), results from external pressure (molding) that causes the skull to become misshapen. It is most often associated with infants sleeping or lying on their backs. Supine positioning is recommended as a strategy to reduce the likelihood of SIDS, and has contributed to the increased incidence of post-natal plagiocephaly. Plagiocephaly can also occur as a feature of other disorders (e.g., craniofacial disorders, torticollis, and cervical anomalies). Positional skull deformities are generally benign, reversible head-shape anomalies that do not require surgical intervention.

POLICY – MPP –Cranial Orthotic Devices

Severe Plagiocephaly: Is defined as an asymmetry of 10 mm or more in one of the following anthropometric measures: cranial vault, skull base, or orbitotragal depth; OR a cephalic index of at least 2 standard deviations above or below the mean for the appropriate gender/age.

GUIDELINES/INSTRUCTIONS

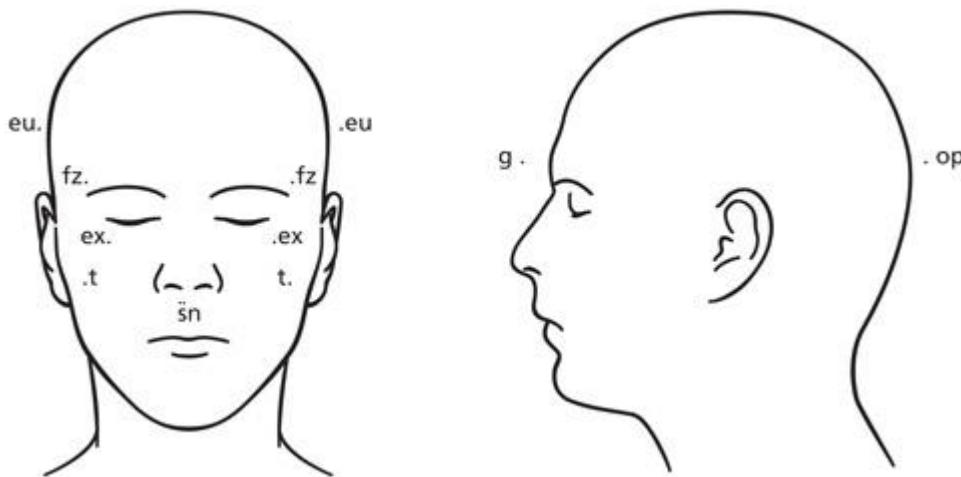
Virginia Premier Health Plan (VPHP) considers the use of a cranial orthotic device to be reconstructive for the treatment of severe plagiocephaly in infants between 3 and 12 months corrected gestational age which have not improved after 2 months of reposition.

1. The initial use of cranial orthoses is considered **reconstructive**:
 - a. To treat non-synostotic skull deformity (including plagiocephaly, scaphocephaly, and brachycephaly) when both (1 and 2) of the following apply:
 - i. The condition results from disease, trauma, congenital or developmental anomalies, or previous medical therapy; **AND**
 - ii. The individual meets the following criteria (a) and (b) and (c):
 1. The infant is at least 3 months of age but not greater than 12 months of age; **AND**
 2. Documented failure of at least two (2) months of conservative therapy which includes either (a) or (b) below:
 - a. Two months of physical therapy for infants with associated cervical motion restriction, including initial and final assessment of range of motion; **OR**
 - b. Two months of home management with repositioning for infants without cervical motion restriction; **AND**
 3. Anthropomorphic measurements (see below) following conservative management with final measurements indicating ONE of the following:
 - a. Symmetry discrepancy of more than 10 mm in cranial vault, skull base, or orbitotragal depth; **OR**
 - b. Cephalic index more than (above or below) two (2) standard deviations from the mean.
 2. A second application of the cranial orthosis is considered **reconstructive** for infants between 6 and 18 months of age when the following criteria (A and B and C) have been met:
 - a. Final post-therapy anthropomorphic measurements (see below) indicating ONE or more of the following (1 or 2):
 - i. Symmetry discrepancy of more than 10 mm in cranial vault, skull base, or orbitotragal depth; **OR**
 - ii. Cephalic index more than (above or below) two (2) standard deviations from the mean; **AND**
 - b. One of the following (1 or 2):
 - i. For infants with associated cervical motion restriction, documentation of physical therapy or home exercise program with interval assessment of range of motion since the initial orthotic application; **OR**
 - ii. For infants without cervical motion restriction, at least two months of home management with repositioning either before or after the initial application; **AND**
 - c. If a new orthosis is being requested, documentation of skin complications or inadequate therapeutic positioning due to head growth that cannot be managed or prevented with refitting of the original orthosis, when continued improvement is anticipated.

Anthropomorphic Measurements:

POLICY – MPP –Cranial Orthotic Devices

Cephalic Index



$$\text{Cephalic index} = \frac{\text{Head width (eu - eu)} \times 100}{\text{Head length (g - op)}}$$

Cephalic index equal to head width eu minus eu multiplied by 100 divided by head length g minus op

Table: Cephalic Index for Male and Female and their age

Sex	Age	-2 SD	-1 SD	Mean	+1 SD	+2 SD
Male	16 days 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	16 days 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

Cranial Vault

[left frontozygomatic point (fz) to right euryon (eu)] minus [right frontozygomatic point (fz) to left euryon (eu)]

Skull Base

[subnasal point (sn) to left tragus (t)] minus [subnasal point (sn) to right tragus (t)]

Orbitotragial Depth

POLICY – MPP –Cranial Orthotic Devices

[left exocanthion point (ex) to left tragus (t)] minus [right exocanthion point (ex) to right tragus (t)]

Medically Necessary:

The use of an adjustable cranial orthosis is considered **medically necessary** in the post-operative management of infants following endoscopic repair of craniosynostosis.

The use of cranial orthoses is considered **medically necessary** as an adjunct to surgical treatment of synostotic skull deformity.

Not Medically Necessary:

The use of cranial orthoses is considered **not medically necessary** when criteria have not been met.

Initial application of cranial orthosis for infants over the age of 12 months is considered **not medically necessary**.

Continued use of cranial orthosis after 18 months of age is considered **not medically necessary**.

Cosmetic and Not Medically Necessary:

The use of cranial orthoses is considered **cosmetic and not medically necessary** for non-surgical treatment of synostotic skull deformities or for infants with craniosynostosis who have not undergone corrective surgery for the fusion.

The use of cranial orthoses is considered **cosmetic and not medically necessary** for infants with unmanaged hydrocephalus (stabilization is required prior to beginning remolding treatment (e.g., shunt placement)).

CODING

HCPCS

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)

ICD-10

Diagnosis

P13.0	Fracture of skull due to birth injury
P15.2	Sternomastoid injury due to birth injury
Q67.3	Plagiocephaly
Q67.4	Other congenital deformities of skull, face and jaw
Q68.0	Congenital deformity of sternocleidomastoid muscle (congenital torticollis)
Q75.0	Craniosynostosis
Q75.9	Congenital malformation of skull and face bones, unspecified

REFERENCES

POLICY – MPP –Cranial Orthotic Devices

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4. Jo Ling Goh, B.A., David F. Bauer, M.D., Susan R. Durham, M.D., and Mitchell A. Stotland, M.D. Orthotic (helmet) therapy in the treatment of plagiocephaly. Neurosurg Focus 35 (4):E2, 2013
5. Deformational plagiocephaly and orthotic treatment: indications and limitations. Patricia Mortenson & Paul Steinbok & David Smith. Childs Nerv Syst (2012) 28:1407–1412 DOI 10.1007/s00381-012-1755-3.
6. https://www.cns.org/guidelines/browse-guidelines-detail/5-role-of-cranial-molding-orthosis-helmet-therapy_ Accessed September 10, 2021

Related Documents

Revision History		
Date	By	Description
8/28/20	Dr. Tamar Springel	Annual Review
9/10/21	Dr. Tamar Springel	Annual review