

09-L0000-02

Original Effective Date: 11/15/00

Reviewed: 04/25/24

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Subject: Cranial Orthosis for Craniosynostoses and Plagiocephaly

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

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.

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.

Several cranial orthotic devices 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.

POSITION STATEMENT:

NOTE: Coverage for cranial orthotic devices (helmets or bands) is subject to the member’s benefit terms. Refer to specific contract language regarding cranial orthotic devices.

A cranial orthotic device (i.e., cranial remodeling band or helmet) **meets the definition of medical necessity** when used as an adjunct postoperative therapy for plagiocephaly with synostosis (i.e., craniosynostosis) after surgery.

A cranial orthotic device **meets the definition of medical necessity** when used in the treatment of moderate to severe plagiocephaly or brachycephaly without synostosis (i.e., craniosynostosis) as evidenced by cranial asymmetry substantiated by a cephalic index* that is at least two standard deviations above or below the mean for the appropriate gender and age **OR** asymmetry of 12 mm or more in the measurement of the cranial vault, skull base, or orbitotragial depth when **ALL** of the following criteria are met:

- The child is between 3 and 18 months old; **AND**
- The child has failed a 2-month trial of conservative therapy (e.g., repositioning the child in a manner where the head is positioned/turned to the opposite side of the deformity, exercises, physical therapy); **AND**
- Photographs demonstrate evidence of moderate to severe plagiocephaly or brachycephaly without synostosis.

*Cephalic Index: The cephalic index, which describes a ratio of the maximum width to the head length expressed as a percentage, is used to assess abnormal head shapes without asymmetry. The maximum width is measured between the most lateral points of the head located in the parietal region. The head length is measured from the most prominent point in the median sagittal plane between the supraorbital ridges to the most prominent posterior point of the occiput, expressed as a percentage. See Table 1 (developed by the American Academy of Orthotists and Prosthetists [AAOP] 2004).

Table 1

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

A second cranial remodeling band or helmet **meets the definition of medical necessity** for children who met the above criteria at the beginning of therapy if the cranial asymmetry has not resolved or significantly improved after 2-4 months.

Cranial remodeling bands or helmets are contraindicated for children 2 years of age and older.

Cranial orthosis, utilizing a cranial remodeling band or helmet, **does not meet the definition of medical necessity** when used as a non-surgical treatment for plagiocephaly or brachycephaly without synostosis (positional plagiocephaly) when used primarily to improve cranial asymmetry for cosmetic outcomes.

The use of these devices to treat or prevent loss of function **does not meet the definition of medical necessity**. There are no conclusive data to support the use of dynamic orthotic cranioplasty devices for improving function or preventing loss of function.

BILLING/CODING INFORMATION:

HCPCS Coding:

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

The following information may be required documentation to support medical necessity: Physician history and physical, physician treatment notes to included documented failed conservative treatment and photographs, treatment plan, operative reports, physical therapy notes (if applicable).

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0,	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician treatment/ visit notes including documentation of failure of conservative medical management	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician operative note	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physical therapy notes	28579-1	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

DEFINITIONS:

Brachiocephaly: Shortened front to back dimension of the skull that results from premature fusion of the coronal suture.

Plagiocephaly: Flattening of the skull on the back or one side of the head. Sagittal suture: Skull joint that separates the left and right halves of the skull.

RELATED GUIDELINES:

[Orthotics, 09-L0000-03](#)

OTHER:

None applicable.

REFERENCES:

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16. U.S. Food & Drug Administration (FDA); accessed at fda.gov.
17. Van Cruchten C, Feijen MM, Van Der Hulst RR. Helmet therapy for positional cranial deformations; a 5-year follow-up study. J Craniomaxillofac Surg. 2022 Jun;50(6):499-503. PMID: 35725060.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/25/24.

GUIDELINE UPDATE INFORMATION:

11/15/00	New Medical Coverage Guideline.
12/06/01	Reviewed – no changes.
10/01/02	4 th quarter HCPCS coding changes.
12/15/02	Reviewed and changed from “cosmetic and non-covered” to “investigational”.
12/15/03	Reviewed; revision to statement regarding When Services Are Not Covered.
12/15/04	Scheduled review; no change in coverage statement.
01/01/06	Scheduled review and annual HCPCS coding update (add 97762; delete 97703); no change in coverage statement.
05/15/06	Unscheduled review and revision to guideline consisting of addition of coverage statement regarding cranial orthoses as adjunct therapy following endoscopic surgery for plagiocephaly with synostosis.
01/01/07	Annual HCPCS coding update (S1040 revised).
05/15/07	Scheduled review; reformatted guideline; removed restriction of “endoscopic” from coverage statement; removed investigational statement regarding use of these

	devices as an adjunct postoperative therapy for plagiocephaly with synostosis after surgery is done endoscopically; updated references.
07/15/08	Scheduled review; position statement unchanged; references updated.
06/15/09	Scheduled review; position statement unchanged; references updated.
12/15/10	Reviewed; position statement revised; formatting changes.
09/15/11	Revision; formatting changes.
01/15/13	Scheduled review; position statement updated; references updated; formatting changes.
02/15/14	Scheduled review; position statement unchanged; Program Exceptions section updated; references updated.
02/15/15	Annual review; position statements unchanged; references updated.
09/15/16	Revision; coding section updated.
06/15/18	Review; position statements maintained; policy title, description section and references updated; formatting changes.
10/15/19	Review; Age range in cranial devices position statement updated; description and references updated.
10/15/21	Review: Position statements maintained and references updated.
05/15/23	Review: Position statements maintained; references updated.
05/15/24	Review: Position statements maintained; description and references updated.