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MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 07/27/05**
SECTION: Durable Medical Equipment (DME)	**LAST REVIEW DATE: 06/24/14**
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	ARCHIVE DATE:

CRANIAL ORTHOSIS

- **Dynamic Orthotic Cranioplasty (DOC)**
- **Cranial Banding**
- **Cranial Helmet**

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Cranial orthosis is a device used for the treatment of deformational plagiocephaly or brachycephaly. It has also been proposed as a post-operative adjunct for synostotic plagiocephaly. The custom-molded device is intended for medical purposes to apply pressure to the prominent regions of an infant's cranium in order to progressively improve cranial symmetry and/or shape. Cranial orthosis is also known as dynamic orthotic cranioplasty (DOC), cranial banding or cranial helmet.

Definitions:

Functional Impairment:
A state in which the normal or proper action (function) of any body part or organ is damaged or deficient as a result of plagiocephaly.

CRANIAL ORTHOSIS (cont.)

Definitions: (cont.)

Brachycephaly:
Refers to a disproportionately short head.

Non-Synostotic:
Asymmetrically shaped head where the cranial sutures remain open. Also known as positional or deformational plagiocephaly. This type can be secondary to various environmental factors including, *but not limited to:*

- Birth trauma, torticollis
- Cervical anomalies
- Premature birth
- Restrictive intrauterine environment
- Sleeping position

Plagiocephaly:
Refers to an asymmetrically shaped head. Can be subdivided into synostotic and non-synostotic types.

Synostotic:
Asymmetrically shaped head due to premature closure of the sutures of the cranium.

Criteria:

COVERAGE FOR TREATMENT TO CORRECT A CONGENITAL DEFECT OR BIRTH ABNORMALITY IS DEPENDENT UPON BENEFIT PLAN LANGUAGE AND IS SUBJECT TO THE PROVISIONS OF THE RECONSTRUCTIVE BENEFIT AND THE COSMETIC BENEFIT EXCLUSION. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS AND THE FUNCTIONAL IMPAIRMENT REQUIREMENT.

- **If benefit coverage for cranial orthosis (cranial band/helmet) is available**, cranial orthosis is considered ***medically necessary*** for **ANY** of the following:

  1. Non-synostotic plagiocephaly or brachycephaly with documentation of the following:

     - Child is 3 months to 18 months of age, **and**
     - Functional impairment, **and**
     - Existence of a condition or situation causing severe deformity or skull shape distortion, e.g., torticollis, that is unresponsive to a minimum of 30 days treatment with therapeutic physical adjustments and position changes.

  2. As a postoperative adjunct to craniosynostotic surgery.

CRANIAL ORTHOSIS (cont.)

Criteria: (cont.)

- **If benefit coverage for cranial orthosis (cranial band/helmet) is available**, replacement of a cranial orthotic due to growth of the child is dependent upon continued functional impairment **and** the continued medical necessity of cranial remodeling.
- Cranial orthosis for a non-functional impairment is considered ***cosmetic*** and ***not eligible for coverage***.
- Cranial orthosis for a child over 18 months of age is not indicated.

An in-network provider is available for this service.

Resources:

1. 1.01.11 BCBS Association Medical Policy Reference Manual. Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses. Re-issue date 05/22/14, issue date 07/31/1997.
2. American Academy of Pediatrics, Laughlin J, et al. "Prevention and Management of Positional Skull Deformities in Infants." Pediatrics 128(6): 1236 -1241.
3. Baumgartner JE, Teichgraeber JF, Waller AL, Grantcherova E, Gateno J, Xia JJ. Microscopic approach to craniosynostosis. *J Craniofac Surg.* 2005;16(6):997-1005.
   Reprint: Abstract
4. BCBS Association Technology Assessment Program. Cranial Orthosis for Plagiocephaly Without Synostosis. 2000;14(21).
5. Sullivan, L. Deformational Plagiocephaly Not Tied to Frequent OM. 2009;43: 12:14.
   Reprint: Full Text
6. van Vlimmeren LA, Helders PJ, van Adrichem LN, Engelbert RH. Torticollis and plagiocephaly in infancy: therapeutic strategies. *Pediatr Rehabil.* 2006;9(1):40-6.
   Reprint: Full Text

CRANIAL ORTHOSIS (cont.)

Resources: (cont.)

FDA Summary Statements for orthosis, cranial. Device names include, but are not limited to:

DOC Band™ (Dynamic Orthotic Cranioplasty)
STARband™

- FDA-approved indication: Intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic, positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphacephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

FDA Summary Statements for orthosis, cranial. Device names include, *but are not limited to:*

Boston Band Cranial Remolding Orthosis

- FDA-approved indication: Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial symmetry and/or shape in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes.

Hanger Cranial Band™

- FDA-approved indication: Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagioccephalic-, brachycephalic-, scaphocephalic-shaped heads.