



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 12/17/14
LAST REVIEW DATE: 04/17/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

CRANIAL ORTHOSIS

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

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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CRANIAL ORTHOSIS (cont.)

Description:

Cranial orthosis is a device used for the treatment of deformational plagiocephaly or brachycephaly and as a postoperative 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.

Brachycephaly:

Refers to a disproportionately short head.

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.

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



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CRANIAL ORTHOSIS (cont.)

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**, use of an adjustable cranial orthosis for synostosis following cranial vault remodeling surgery is considered **medically necessary**.
- **If benefit coverage for cranial orthosis (cranial band/helmet) is available**, use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered **not medically necessary**.
- **If benefit coverage for cranial orthosis (cranial band/helmet) is available**, use of an adjustable cranial orthosis as a treatment of plagiocephaly or brachycephaly without synostosis is considered **not medically necessary**.

An in-network provider is available for this service.

Resources:

Literature reviewed 04/17/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.01.11 BCBS Association Medical Policy Reference Manual. Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses. Re-issue date 03/08/2018, issue date 07/31/1997.
2. American Academy of Pediatrics Clinical Report: Prevention and management of positional skull deformities in infants. *Pediatrics*. Dec 2011;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 Nov 2005;16(6):997-1005.



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CRANIAL ORTHOSIS (cont.)

Resources: (cont.)

4. BCBS Association Technology Assessment Program. Cranial Orthosis for Plagiocephaly Without Synostosis. 02/2000;14(21).
5. Sullivan L. Deformational Plagiocephaly Not Tied to Frequent OM. 2009/12/01 2009;43(12):14.
6. UpToDate:. Overview of Craniosynostosis. June 10, 2016.
7. van Vlimmeren LA, Helders PJ, van Adrichem LN, Engelbert RH. Torticollis and plagiocephaly in infancy: therapeutic strategies. *Pediatr Rehabil.* Jan-Mar 2006;9(1):40-46.
8. Wilbrand JF, Lautenbacher N, Pons-Kuhnemann J, et al. Treated Versus Untreated Positional Head Deformity. *J Craniofac Surg.* Jan 2016;27(1):13-18.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

