MEDICAL POLICY

POLICY TITLE	ADJUSTABLE CRANIAL ORTHOSES FOR POSITIONAL PLAGIOCEPHALY AND CRANIOSYNOSTOSES
POLICY NUMBER	MP 6.056

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**10/1/2025**

I. POLICY

Use of an adjustable cranial orthosis may be considered **medically necessary** following cranial vault remodeling surgery for synostosis.

Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly without synostosis may be considered **medically necessary** when all the following conditions have been met:

- The individual is between 3 and 18 months old; **AND**
- There is documented failure of conservative therapy (repositioning and physical therapy) of at least 2 months duration; **AND**
- The individual has a cephalic index that is at least two standard deviations above or below the mean for the appropriate gender and age

Use of an adjustable cranial orthosis is considered **investigational** for all other indications not outlined above. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

(See Policy Guidelines below for information related to use of an adjustable cranial orthosis as a reconstructive service).

Policy Guidelines

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 (i.e., improve health outcomes). In this policy, 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.

Assessment of plagiocephaly in research studies may be based on anthropomorphic measures of the head, using anatomic and bony landmarks. Although, there is no accepted minimum objective level of asymmetry for a plagiocephaly diagnosis there are definitions that have been adopted by convention:

- Brachiocephaly: Shortened front to back dimension of the skull that results from premature fusion of the coronal suture
- Cranial base: Asymmetry of the cranial base is measured from the subnasal point (midline under the nose) to the tragus (the cartilaginous projection in front of the external auditory canal
- 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 (i.e., euryon). The head length is measured from the most prominent point in the median sagittal plane between the supraorbital ridges (i.e., glabella) to the most prominent posterior point of the occiput (i.e., the opisthocranion), expressed as a percentage. The cephalic index can then be compared to normative measures for age and gender. See Table PG1 (as developed by American Academy of Orthotists and Prosthetists 2004).
- Cranial Vault Asymmetry: is assessed by measuring from the frontozygomaticus point (identified by palpation of the suture line above the upper outer corner of the orbit) to the euryon, defined as the most lateral point on the head located in the parietal region. The cranial vault asymmetry index (CAVI) can be used to assess cranial shape and is calculated by taking the difference between the diagonals of the head (measured from the anthropometric points), dividing by the larger diagonal, and multiplying by 100 to get a percentage. The Children's Healthcare of Atlanta plagiocephaly severity scale, based on clinical presentation and CAVI, was developed in 2017 to assist with clinical treatment recommendations and is shown in Table PG2.
- 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.

Table PG1. Cephalic Index

Sex	Age	-2SD	-1SD	Mean	+1SD	+2SD
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

Table PG2. Children's Healthcare of Atlanta Plagiocephaly Severity Scale

Level	Clinical Presentation	Recommendations	CVAI
1	All symmetry within normal limits	No treatment required	<3.5
2	Minimal asymmetry in one posterior quadrant No secondary changes	Repositioning program	3.5 to 6.25
3	Two quadrant involvement Moderate to severe posterior quadrant flattening Minimal ear shift and/or anterior involvement	Conservative treatment: Repositioning Cranial remolding orthosis (based on age and history)	6.25 to 8.75
4	Two or three quadrant involvement Severe posterior quadrant flattening Moderate ear shift Anterior involvement including noticeable orbit asymmetry	Conservative treatment: Cranial remolding orthosis	8.75 to 11
5	Three or four quadrant involvement Severe posterior quadrant flattening Severe ear shift Anterior involvement including orbit and cheek asymmetry	Conservative treatment: Cranial remolding orthosis	> 11

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

Cranial orthoses involve an adjustable helmet or band that progressively molds the shape of the infant cranium by applying corrective forces to prominences while leaving room for growth in the adjacent flattened areas. A cranial orthotic device may be used to treat postsurgical synostosis or positional plagiocephaly in pediatric patients.

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.

Treatment
Synostotic deformities associated with functional deficits are addressed by surgical remodeling of the cranial vault. The remodeling (reshaping) is accomplished by opening and expanding the abnormally fused bone.

In a review of the treatment of craniosynostosis, Persing (2008) indicated that premature fusion of one or more cranial vault sutures occurs in approximately 1 in 2500 births. Of these craniosynostoses, asymmetric deformities involving the cranial vault and base (e.g., unilateral coronal synostosis) will have a higher rate of postoperative deformity, which would require additional surgical treatment. Persing (2008) suggested that use of cranial orthoses postoperatively may serve 2 functions: (1) they protect the brain in areas of large bony defects, and (2) they may remodel the asymmetries in skull shape, particularly when the bone segments are more mobile.

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.

Regulatory Status
Multiple cranial orthoses (helmets) 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. FDA product code: MVA.

IV. RATIONALE

TOP

Summary of Evidence

For individuals who have open or endoscopic surgery for craniosynostosis who receive a postoperative cranial orthosis, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Overall, the evidence on the efficacy of cranial orthoses following endoscopic-assisted or open cranial vault remodeling surgery for craniosynostosis is limited. However, functional impairments are related to craniosynostosis, and there is a risk of harm from additional surgery when severe deformity has not been corrected. Because cranial orthoses can facilitate remodeling, use of a cranial orthosis is likely to improve outcomes after cranial vault remodeling for synostosis. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have positional plagiocephaly who receive a cranial orthosis, the evidence includes a comparative study and case series. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Overall, evidence on an association between positional plagiocephaly and health outcomes is limited. The largest controlled study found no difference in function between infants with plagiocephaly and age-matched concurrent controls. Taking into consideration the limited number of publications over the past decade and the low likelihood of development of high-level evidence from controlled studies, the scientific literature is limited in support of an effect of deformational plagiocephaly on functional health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

TOP

N/A

VI. DISCLAIMER

TOP

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

VII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
S1040							

ICD-10-CM Diagnosis Code	Description
M43.6	Torticollis
Q67.3	Plagiocephaly
Q67.4	Other congenital deformities of skull, face and jaw
Q75.001	Craniosynostosis unspecified, unilateral
Q75.002	Craniosynostosis unspecified, bilateral
Q75.009	Craniosynostosis unspecified
Q75.01	Sagittal craniosynostosis
Q75.021	Coronal craniosynostosis unilateral
Q75.022	Coronal craniosynostosis bilateral
Q75.029	Coronal craniosynostosis unspecified
Q75.03	Metopic craniosynostosis
Q75.041	Lambdoid craniosynostosis, unilateral
Q75.042	Lambdoid craniosynostosis, bilateral
Q75.049	Lambdoid craniosynostosis, unspecified
Q75.051	Cloverleaf skull
Q75.052	Pansynostosis
Q75.058	Other multi-suture craniosynostosis
Q75.08	Other single suture craniosynostosis
Q75.8	Other specified congenital malformations of skull and face bones
Q75.9	Congenital malformation of skull and face bones, unspecified

VIII. REFERENCES

TOP

1. *Holowka MA, Reisner A, Giavedoni B, et al. Plagiocephaly Severity Scale to Aid in Clinical Treatment Recommendations. J Craniofac Surg. May 2017; 28(3): 717-722. PMID 28468155*

2. Persing JA. MOC-PS(SM) CME article: management considerations in the treatment of craniosynostosis. Plast Reconstr Surg. Apr 2008;121(4 Suppl):1-11. PMID 18379381
3. Kaufman BA, Muszynski CA, Matthews A, et al. The circle of sagittal synostosis surgery. Semin Pediatr Neurol. Dec 2004;11(4):243-248. PMID 15828707
4. Stevens PM, Hollier LH, Stal S. Post-operative use of remoulding orthoses following cranial vault remodelling: a case series. Prosthet Orthot Int. Dec 2007;31(4):327-341. PMID 18050005
5. Jimenez DF, Barone CM, Cartwright CC, et al. Early management of craniosynostosis using endoscopic-assisted strip craniectomies and cranial orthotic molding therapy. Pediatrics. Jul 2002;110(1 Pt 1):97-104. PMID 12093953
6. Jimenez DF, Barone CM. Early treatment of anterior calvtimes craniosynostosis using endoscopic-assisted minimally invasive techniques. Childs Nerv Syst. Dec 2007;23(12):1411-1419. PMID 17899128
7. Jimenez DF, Barone CM. Endoscopic technique for sagittal synostosis. Childs Nerv Syst. Sep 2012;28(9):1333- 1339. PMID 22872245
8. Jimenez DF, Barone CM. Multiple-suture nonsyndromic craniosynostosis: early and effective management using endoscopic techniques. J Neurosurg Pediatr. Mar 2010;5(3):223-231. PMID 20192637
9. Gociman B, Marengo J, Ying J, et al. Minimally invasive strip craniectomy for sagittal synostosis. J Craniofac Surg. May 2012;23(3):825-828. PMID 22565892
10. Honeycutt JH. Endoscopic-assisted craniosynostosis surgery. Semin Plast Surg. Aug 2014;28(3):144-149. PMID 25210508
11. Shah MN, Kane AA, Petersen JD, et al. Endoscopically assisted versus open repair of sagittal craniosynostosis: the St. Louis Children's Hospital experience. J Neurosurg Pediatr. Aug 2011;8(2):165-170. PMID 21806358
12. Chan JW, Stewart CL, Stalder MW, et al. Endoscope-assisted versus open repair of craniosynostosis: a comparison of perioperative cost and risk. J Craniofac Surg. Jan 2013;24(1):170-174. PMID 23348279
13. van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, et al. Helmet therapy in infants with positional skull deformation: randomised controlled trial. BMJ. May 1 2014;348:g2741. PMID 24784879
14. McGarry A, Dixon MT, Greig RJ, et al. Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly. Dev Med Child Neurol. Aug 2008;50(8):568-576. PMID 18754893
15. Mulliken JB, Vander Woude DL, Hansen M, et al. Analysis of posterior plagiocephaly: deformational versus synostotic. Plast Reconstr Surg. Feb 1999;103(2):371-380. PMID 9950521
16. Loveday BP, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? J Craniofac Surg. Jul 2001;12(4):308-313. PMID 11482615
17. Xia JJ, Kennedy KA, Teichgraeber JF, et al. Nonsurgical treatment of deformational plagiocephaly: a systematic review. Arch Pediatr Adolesc Med. Aug 2008;162(8):719-727. PMID 18678803
18. Graham JM, Jr., Gomez M, Halberg A, et al. Management of deformational plagiocephaly: repositioning versus orthotic therapy. J Pediatr. Feb 2005;146(2):258-262. PMID 15689920

19. *Kluba S, Kraut W, Calgeer B, et al. Treatment of positional plagiocephaly--helmet or no helmet? J Craniomaxillofac Surg. Jul 2014;42(5):683-688. PMID 24238984*
20. *Couture DE, Crantford JC, Somasundaram A, et al. Efficacy of passive helmet therapy for deformational plagiocephaly: report of 1050 cases. Neurosurg Focus. Oct 2013;35(4):E4. PMID 24079783*
21. *Fowler EA, Becker DB, Pilgram TK, et al. Neurologic findings in infants with deformational plagiocephaly. J Child Neurol. Jul 2008;23(7):742-747. PMID 18344457*
22. *Panchal J, Amirsheybani H, Gurwitch R, et al. Neurodevelopment in children with single-suture craniosynostosis and plagiocephaly without synostosis. Plast Reconstr Surg. Nov 2001;108(6):1492-1498; discussion 1499-1500. PMID 11711916*
23. *Miller RI, Clarren SK. Long-term developmental outcomes in patients with deformational plagiocephaly. Pediatrics. Feb 2000;105(2):E26. PMID 10654986*
24. *Shamji MF, Fric-Shamji EC, Merchant P, et al. Cosmetic and cognitive outcomes of positional plagiocephaly treatment. Clin Invest Med. Oct 6 2012;35(5):E266. PMID 23043707*
25. *Tamber MS, Nikas D, Beier A, et al. The Role of Cranial Molding Orthosis (Helmet) Therapy. 2016*
26. *Tamber MS, Nikas D, Beier A, et al. Guidelines: Congress of Neurological Surgeons systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. Neurosurgery. Nov 2016;79(5):E632-E633. PMID 27759675*
27. *National Institute of Neurological Disorders and Stroke (NINDS). Craniosynostosis Information Page. 2019*

IX. POLICY HISTORY

TOP

MP 6.056	**08/06/2020 Consensus Review.** No changes to policy statements.
	05/13/2021 Consensus Review. No changes to policy statements. References updated.
	06/21/2022 Consensus Review. No change to policy statement. References reviewed and updated. Product Variations updated.
	05/16/2023 Consensus Review. No change to policy statement. Background, Rationale and References updated.
	09/11/2023 Administrative Update. Added ICD10 codes Q75.001, Q75.002, Q75.009, Q75.01, Q75.021, Q75.022, Q75.029, Q75.03, Q75.041, Q75.042, Q75.049, Q75.051, Q75.052, Q75.058, Q75.08. Effective 10/01/2023
	05/29/2024 Consensus Review. Policy Guidelines and Rationale updated. Reference added.
	04/03/2025 Minor Review. The asymmetry criteria and the criteria addressing subsequent cranial orthoses were removed. Benefit Variation and Disclaimer updated.
	07/10/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.

POLICY TITLE	ADJUSTABLE CRANIAL ORTHOSES FOR POSITIONAL PLAGIOCEPHALY AND CRANIOSYNOSTOSES
POLICY NUMBER	MP 6.056

TOP