

MEDICAL POLICY – 1.01.506

Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses

BCBSA Ref Policy: 1.01.11

Effective Date: **Feb. 6, 2026***

Last Revised: Oct. 14, 2025

Replaces: 1.01.11

RELATED MEDICAL POLICIES:

None

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Introduction

A newborn baby's skull is made up of several bones that are not yet solidly connected to each other. This allows the infant's skull to grow and get bigger as the baby's brain grows. Sometimes, the baby's skull may have become flattened or misshaped during the birthing process or for other reasons. This abnormal skull shape is called plagiocephaly. Adjustable helmets (a cranial orthotic) may be used to reshape flattened areas of a baby's skull. However, there is no medical evidence that a child's development is affected by a head that is not exactly the same shape on both sides. Using a helmet in this situation is cosmetic.

The skull bones may also fuse together too soon. This is dangerous, as it will not allow the brain to grow inside this solid skull. This can cause brain damage, developmental delay, and problems with thinking. Fusion of the skull bones is called synostosis. Surgery is needed to open up the space between the skull bones to allow the brain to grow normally. Helmets may be used after skull surgery to help protect the brain and reshape the bones.

This policy describes when an adjustable helmet may be medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can

be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Treatment	Medical Necessity
Adjustable cranial orthosis for synostosis	Use of an adjustable cranial orthosis (cranial banding or soft shell helmet) may be considered medically necessary following cranial vault remodeling surgery for synostosis for postoperative care. Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered not medically necessary.
Adjustable cranial orthosis for plagiocephaly without synostosis	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 criteria are met: • The child is aged between 3 and 18 months • The device is custom made and fitted for the child • The child has severe positional plagiocephaly* that has not responded to a two-month trial of repositioning and/or physical therapy *Severe plagiocephaly is defined by the following: • 10 mm or more of asymmetry in one of the following measures: cranial vault, skull base, or orbitotragial depth (see Table 1 below) OR • Cephalic index at least two standard deviations above or below the mean for the appropriate gender and age (see Table 2 below)



Treatment	Medical Necessity
	Use of an adjustable cranial orthosis is considered not medically necessary for all other indications not outlined above. Note: A protective helmet (HCPCS code A8000-A8004) is not a cranial orthosis/cranial remolding device. It is considered a safety device worn to prevent injury to the head. It is not addressed in this policy.
A second cranial orthosis is requested	A second cranial orthosis as a treatment of persistent plagiocephaly may be considered medically necessary after two months of use of the initial cranial orthosis if documentation shows there are skin complications or head growth that cannot be managed with refitting of the original orthosis.

Evaluation of Plagiocephaly

The diagnosis of the type of craniosynostosis is confirmed through physical examination and imaging studies.

Anthropometric data, or the measurements used to evaluate abnormal head shape by measuring the distance in mm from one pre-designated point on the face or skull to another must document moderate to severe plagiocephaly.

The evaluation of cranial asymmetry may be based on one or more of four anthropometric measures: cranial vault, skull base, orbitotragial depth measurements or the cephalic index.

Table 1. Anthropometric Measurements

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



Evaluation of cranial asymmetry may be based on the cephalic index, a ratio between the width and length of the head. Typically, head width is calculated by subtracting the distance from euryon (eu) on one side of the head to euryon on the other side of head and multiplying by 100. Head length is generally calculated by measuring the distance from glabella point (g) to opisthocranion point (op). The cephalic index is then calculated as:

- Head width (eu – eu) x 100
- Head length (g – op)

The cephalic index is considered abnormal if it is two standard deviations above or below the mean measurements (Farkas and Munro, 1987).

Table 2. Cephalic Index

Cephalic Index (AAOP, 2004)						
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
	13 – 18 Months	Apply the 12-month measurements for children 13-18 months of age				
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
	13 – 18 Months	Apply the 12 month measurements for children 13-18 months of age				

SD: standard deviation. Developed by the American Academy of Orthotists and Prosthetists 2004

Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The records should include the following:

- One of the following must be present:



Documentation Requirements

- Child had surgery for craniosynostosis (the bones in the child's skull join together too early), and the cranial orthosis is needed for post-operative care
- OR**
- The child has persistent plagiocephaly (the child's head is flat in the back or on one side) or brachycephaly (shortened front to back dimension of the skull) without synostosis (fusion of the two bones):
 - Child's age is between 3 and 18 months old
 - Cephalic index is at least two standard deviations above or below the mean (for the appropriate gender and age)
 - The persistent plagiocephaly or brachycephaly without synostosis has not responded to a 2-month trial of repositioning and/or physical therapy

Coding

Code	Description
HCPCS	
S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Consideration of Age

The ages referenced in this policy for which cranial orthoses are considered medically necessary are between 3 and 18 months. This is based on the FDA-approved age range for these helmets and the American Academy of Pediatrics (AAP) states, "The use of helmets and other related devices seems to be beneficial primarily when there has been a lack of response to mechanical adjustments and exercises, and the best response to helmets occurs in the age range of 4 to 12 months of age."



Definition of Terms

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

Congenital anomaly: A marked difference from the normal structures of an infant's body part, that's present from birth and manifests during infancy.

Coronal suture: Skull joint that goes across the top of the skull and separates the front and back halves of the skull

Cosmetic: cosmetic services are those which are primarily intended to preserve or improve appearance. Cosmetic surgery is performed to reshape normal structures of the body in order to improve the individual's appearance or self-esteem.

Craniosynostosis: Fusion of at least two of the skull bones before the brain has fully formed.

Metopic suture: Skull joint that separates the left and right halves of the forehead.

Orbitotragial depth: Asymmetry of the orbitotragial depth is measured from the exocanthion (outer corner of the eye fissure where the eyelids meet) to the tragus (the cartilaginous projection in front of the external auditory canal).

Physical functional impairment: physical functional impairment means either limitation from normal physical functioning or baseline level of functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of nearby body part(s) or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments.

Plagiocephaly: Flattening of the skull on the back or one side of the head.

Reconstructive surgery: reconstructive surgery refers to surgeries performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function.

Sagittal suture: Skull joint that separates the left and right halves of the skull.



Synostosis: Fusion of two bones.

Benefit Application

Depending on contract language, use of an adjustable cranial orthosis for nonsynostotic plagiocephaly may be considered reconstructive or cosmetic. In general, when functional impairment is present, its treatment would be considered medically necessary. However, if a functional impairment is not present, its treatment would be considered cosmetic. Refer to the member contract language for benefit determination.

Evidence Review

Description

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 individuals.

Background

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 increased intracranial pressure in an abnormally or asymmetrically shaped cranium. The type and degree of craniofacial deformity depend 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.² 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 two 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 the 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.



Summary of Evidence

For individuals who have open or endoscopic surgery for craniosynostosis who receive a postoperative cranial orthosis, the evidence includes case series. The 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. The relevant outcomes are a 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.

Additional Information

2008 Input

Multiple medical organization guidelines have supported use of orthoses for positional plagiocephaly with criteria. The conditions for which the medical organizations noted that use of helmets and related devices seem to be primarily beneficial may, therefore, be considered medically necessary.



Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy is listed in [Table 3](#).

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06173102	Treatment Effectiveness of Cranial Orthosis Therapy in the Correction of Deformational Plagiocephaly: a Randomized Controlled Pilot Study Comparing Cranial Orthosis Therapy to the Natural Course	24	Oct 2024
NCT05917678	Effectiveness of Repositioning, Physical Therapy, and Cranial Remolding in Infants With Cranial Deformation	65	Jul 2027
NCT06762691	Cranial Remolding Orthosis Registry	500	Apr 2030
Unpublished			
NCT02370901^a	Cranial Orthotic Device Versus Repositioning Techniques for the Management of Plagiocephaly: the CRANIO Randomized Trial	226	Nov 2022 (last updated Nov 2021)

^a Denotes industry-sponsored or cosponsored trial

NCT: national clinical trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from three physician specialty societies (four reviews) and two academic medical centers while this policy was under review in 2008. Input was



mixed about whether the use of helmets or adjustable banding for treatment of plagiocephaly or brachycephaly without synostosis should be considered medically necessary or not medically necessary. Clinical input agreed that cranial orthoses may be indicated following cranial vault surgery.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Congress of Neurological Surgeons and Section on Pediatric Neurosurgery

In 2016, the Congress of Neurological Surgeons and the Section on Pediatric Neurosurgery commissioned a systematic review to inform a joint evidence-based guideline on the role of cranial molding orthosis therapy for individuals with positional plagiocephaly.^{25,26} The guideline was issued by a multidisciplinary task force that included clinical and methodological experts; all task force members were required to disclose potential conflicts of interest. The guideline was endorsed by the Joint Guidelines Committee of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons and American Academy of Pediatrics (AAP).

The guideline provided level II recommendations (uncertain clinical certainty) on the use of helmet therapy “for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy)” and “for infants with moderate to severe plagiocephaly presenting at an advanced age.” The recommendations were based on a randomized controlled trial, five prospective comparative studies, and nine retrospective comparative studies (all rated as class II evidence).



National Institute of Neurological Disorders and Stroke

In 2019, the National Institute of Neurological Disorders and Stroke has stated that "Treatment for craniosynostosis generally consists of surgery to improve the symmetry and appearance of the head and to relieve pressure on the brain and the cranial nerves [although] for some children with less severe problems, cranial molds can reshape the skull to accommodate brain growth and improve the appearance of the head."²⁷

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Multiple cranial orthoses (helmets) have been cleared for marketing by the US 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 three 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.

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History

Date	Comments
05/19/98	Add to Durable Medical Equipment Section - New policy--replaces BCBSA 1.01.11
01/04/99	Replace Policy - Policy reviewed; no changes made.
06/27/00	Replace Policy - Updated with reference to 1999 TEC Assessment; policy statement unchanged.
12/21/00	Replace Policy - Policy revised and criteria added.
07/01/02	Replace Policy - Policy reviewed with no criteria changes.
10/16/03	Replace Policy - Policy reviewed; additional rationale language and references; policy statement changed from investigational to not medically necessary as adjunctive postsurgical therapy for synostotic plagiocephaly. Notification required prior to publishing (2/15/04).
09/01/04	Replace Policy - Policy renumbered from PR.1.01.106; no date changes.
09/14/04	Replace Policy - Policy reviewed with literature search. Guidelines, Rationale and References updated.
08/09/05	Replace Policy - Policy reviewed with literature search; Rationale updated; no change to policy statement.
02/06/06	Codes updated - No other changes.
05/26/06	Update Scope and Disclaimer - No other changes.
08/08/06	Replace Policy - Policy updated with literature search; no change to policy statement.
02/23/07	Codes Updated - No other changes.
05/08/07	Replace Policy - Policy updated with literature review; no change in policy statement. Reviewed by practicing pediatrician.



Date	Comments
06/10/08	Replace Policy - Policy updated with literature search. References added. Policy statement revised to allow helmets or bands only for endoscopic strip craniectomy as medically necessary. .
11/11/08	Update Rationale section - No other changes.
06/09/09	Replace policy - Policy updated with additional AAP Guideline reference. No change to policy statement.
05/11/10	Replace Policy - Policy updated with literature search. Reference added. No change to policy statement.
06/13/11	Archive Policy. - Policy updated with literature review; no change in policy statement. Reviewed by practicing pediatrician. This policy has been archived.
12/08/15	New Policy. Adopting to support medical necessary indications; excluded in contract language. Policy effective date is May 1, 2016 following provider notification.
04/20/16	Annual review. Policy updated with literature review. Coverage criteria expanded; assessment information moved from policy guidelines to policy section.
11/08/16	Minor update. Language added to the Rationale section to indicate that the applicable age range of this policy is based on FDA-approval for these helmets and is supported by the American Academy of Pediatrics (AAP).
02/01/17	Annual Review, approved January 10, 2017. Policy updated with literature review through September 26, 2016; no references added. Policy statements unchanged.
03/24/17	Policy moved into new format; no change to policy statements.
10/01/17	Annual Review approved September 21, 2017. Policy updated with literature review through June 22, 2017; references 25-26 added. Policy statements unchanged. *Varies slightly from BCBSA.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Minor edits for clarity. Otherwise, policy statements unchanged
09/01/18	Minor update. Re-added Consideration of Age information; it was inadvertently removed in a previous update.
10/01/19	Annual Review, approved September 5, 2019. Policy updated with literature review through January 2019; no references added. Policy statement edited from the child has severe positional plagiocephaly to persistent plagiocephaly or brachycephaly without synostosis for greater clarity. Other statements edited for clarity and conciseness; intent was unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.



Date	Comments
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021; approved October 13, 2020. Policy updated with literature review through May, 2020; no references added. Policy statements unchanged.
06/01/21	Annual Review, approved May 20, 2021. Policy updated with literature search through January 24, 2021; references added. Medical necessity policy statements edited for greater ease of understanding; policy intent essentially unchanged.
06/01/22	Annual Review, approved May 9, 2022. Policy updated with literature search through January 12, 2022; no references added. Policy statements unchanged.
06/01/23	Policy renumbered, approved May 9, 2023, from 1.01.11 to 1.01.506 Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses. Policy updated with literature search December 19, 2022; no references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
12/01/23	Interim Review, approved November 14, 2023. Clarified that a cranial orthosis is considered medically necessary following cranial vault remodeling surgery for synostosis apart from any age criterion. Remainder of the policy statements remain unchanged.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through January 30, 2024; no references added. Policy statements unchanged.
06/01/25	Annual Review, approved May 12, 2025. Policy updated with literature review through January 15, 2025; no references added. Policy statements unchanged except for minor edit Policy intent unchanged.
11/01/25	Interim Review, approved October 14, 2025, effective for dates of service on or after February 6, 2026, following 90-day provider notification. Added policy statement for second cranial orthosis as a treatment of persistent plagiocephaly after 2 months of use of the initial cranial orthosis may be considered medically necessary when criteria are met.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.



Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

