DRAFT Medical Coverage Policy | Cranial Orthoses (Adjustable) for Positional Plagiocephaly and Craniosynostoses

EFFECTIVE DATE: 12|01|2025
POLICY LAST REVIEWED: 08/06/2025

OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

Medicare Advantage Plans and Commercial

Use of an adjustable cranial orthosis may be considered medically necessary:

1. Following cranial vault remodeling surgery for synostosis; OR,
2. For treatment of persistent plagiocephaly or brachycephaly without synostosis.

Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

For all other indications not outlined above, the use of an adjustable cranial orthosis is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

Blue Cross Blue Shield of Rhode Island maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to BCBSRI upon request. Failure to produce the requested information may result in denial or retraction of payment.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable durable medical equipment benefits/coverage.

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 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 (eg, unilateral coronal synostosis) will have a higher rate of postoperative deformity, which would require additional surgical treatment. Persing 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.

Treatment

It is estimated that about two-thirds of plagiocephaly cases may auto-correct spontaneously after regular changes in sleeping position or following physical therapy aimed at correcting neck muscle imbalance. A cranial orthotic device is usually requested after a trial of repositioning fails to correct the asymmetry, or if the child is too immobile for repositioning.

Cranial Orthoses for Positional Plagiocephaly

Results from the HElmet therapy Assessment in Deformed Skulls trial have suggested that, in a practice setting, the effectiveness of cranial orthoses may not differ from the natural course of development for infants with moderate to severe plagiocephaly and brachycephaly. However, the validity of these results is limited by the low percentage of infants who wore the cranial orthoses for the duration of the trial and the relatively low percentage of infants who achieved recovery in either group. In addition, the efficacy of cranial orthoses in infants with very severe plagiocephaly was not addressed. A few reports have assessed the association between positional plagiocephaly and functional impairments. The largest controlled study found no difference in function between infants with plagiocephaly and age-matched concurrent controls. While some series have suggested an association between plagiocephaly and developmental delay, they lacked controls and did not evaluate the possible causal relation to observed association. Results of a study on right-sided verses left-sided plagiocephaly suggested an association between left-sided and functional performance but these results have not been confirmed. During the 2019 update for this policy, although the evidence limitations were acknowledged, given that multiple medical organization guidelines have supported use of orthoses for positional plagiocephaly with criteria, use of cranial orthoses were made medically necessary for certain conditions.

Regulatory Status

Multiple cranial orthoses (helmets) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the510(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.

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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. Not all benefit contracts include benefits for reconstructive services as defined herein.

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). The policy criteria requiring an individual to have a cephalic index of 2standard deviations above or below the mean for the use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly was based on populations included within the evidence base.
- 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 100to 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.
- 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.

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 a meaningful 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 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

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deformational plagiocephaly on functional health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS code(s) is medically necessary when filed with a covered diagnosis:

S1040 Cranial remolding orthosis, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s).

Covered ICD-10 Diagnoses

Q67.3
Q75.001-Q75.8

RELATED POLICIES

None

PUBLISHED

Provider Update, October 2025
Provider Update, October 2024
Provider Update, June 2023
Provider Update, July 2022
Provider Update, December 2021

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