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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustable cranial orthosis</td>
<td>Use of an adjustable cranial orthosis may be considered medically necessary following cranial vault remodeling surgery for synostosis.</td>
</tr>
<tr>
<td></td>
<td>Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered not medically necessary.</td>
</tr>
<tr>
<td></td>
<td>Use of an adjustable cranial orthosis as a treatment of persistent plagiocephaly or brachycephaly without synostosis may be considered medically necessary when all of the following conditions have been met:</td>
</tr>
<tr>
<td></td>
<td>• The patient is between 3 and 18 months old</td>
</tr>
<tr>
<td></td>
<td>• Documented failure of conservative therapy (repositioning and/or physical therapy) of at least 2 months duration</td>
</tr>
<tr>
<td></td>
<td>• The patient has a cephalic index that is at least two standard deviations above or below the mean for the appropriate gender and age (see Table 1 below)</td>
</tr>
<tr>
<td></td>
<td>Use of an adjustable cranial orthosis is considered not medically necessary for all other indications not outlined above.</td>
</tr>
<tr>
<td>Note:</td>
<td>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.</td>
</tr>
</tbody>
</table>
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 1. Cephalic Index

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age</th>
<th>- 2 SD</th>
<th>- 1SD</th>
<th>Mean</th>
<th>+ 1SD</th>
<th>+ 2SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>16 days – 6 months</td>
<td>63.7</td>
<td>68.7</td>
<td>73.7</td>
<td>78.7</td>
<td>83.7</td>
</tr>
<tr>
<td></td>
<td>6 – 12 Months</td>
<td>64.8</td>
<td>71.4</td>
<td>78.0</td>
<td>84.6</td>
<td>91.2</td>
</tr>
<tr>
<td></td>
<td>13 – 18 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Apply the 12-month measurements for children 13-18 months of age</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 days – 6 months</td>
<td>63.9</td>
<td>68.6</td>
<td>73.3</td>
<td>78.0</td>
<td>82.7</td>
</tr>
<tr>
<td></td>
<td>6 – 12 Months</td>
<td>69.5</td>
<td>74.0</td>
<td>78.5</td>
<td>83.0</td>
<td>87.5</td>
</tr>
<tr>
<td></td>
<td>13 – 18 Months</td>
<td></td>
<td></td>
<td></td>
<td>Apply the 12 month measurements for children 13-18 months of age</td>
<td></td>
</tr>
</tbody>
</table>

**Documentation Requirements**

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

- Child age is between 3 and 18 months old
- **AND** one of the following must be present:
  - 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
Documentation Requirements

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):
  - Cephalic index 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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1040</td>
<td>Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)</td>
</tr>
</tbody>
</table>

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Related Information

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 (ie, 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. Table 2 presents normative values and the mean pretreatment
asymmetries reported in large case series. These may be useful in determining if a significant variation from normal is present.

**Table 2. Pretreatment Asymmetries Reported in Large Case Series**

<table>
<thead>
<tr>
<th>Study</th>
<th>Cranial Base, mm</th>
<th>Cranial Vault, mm</th>
<th>Orbitotragial Distance, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moss (1997)¹</td>
<td>NR</td>
<td>9.2</td>
<td>7.1¹</td>
</tr>
<tr>
<td>Littlefield et al. (1998)²</td>
<td>6.17</td>
<td>8.50</td>
<td>4.36</td>
</tr>
<tr>
<td>Teichgraeber et al. (2002)³</td>
<td>7.08</td>
<td>8.53</td>
<td>3.12</td>
</tr>
</tbody>
</table>

NR: not reported.
¹ In this report, the asymmetry was measured from the tragus to the frontozygomatic point instead of the exocanthion.

**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**

*Anthropomorphic Assessment of Plagiocephaly*

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

**Coronal suture:** Skull joint that goes across the top of the skull and separates the front and back halves of the skull
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 cranial index can then be compared to normative measures.

Cranial vault asymmetry: 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.

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).

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.

Synostosis: Fusion of two bones.

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 patients.

Background

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.

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 (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 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.

**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 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. The 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 the effects of the technology on health outcomes. However, during the 2019 update for this policy, professional society clinical input was sought with a response that acknowledged the evidence limitations but an endorsement of current professional guidelines.

Ongoing and Unpublished Clinical Trials

A currently ongoing trial that might influence this policy is listed in Table 3.

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>Cranial Orthotic Device Versus Repositioning Techniques for the Management of Plagiocephaly: the CRANIO Randomized Trial</td>
<td>226</td>
<td>Nov 2020</td>
</tr>
</tbody>
</table>

* 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

**Congress of Neurological Surgeons et al.**

The Congress of Neurological Surgeons and the Section on Pediatric Neurosurgery (2016) published a joint evidence-based guideline on the role of cranial molding orthosis therapy for patients with positional plagiocephaly.\(^{25,26}\) 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**

The National Institute of Neurological Disorders and Stroke (2017) 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.”\(^{27}\)

**National Health Service Quality Improvement**

Scotland’s National Health Service Quality Improvement (2007) issued an evidence note on the use of cranial orthosis treatment for infant deformational plagiocephaly.\(^{28}\) No evidence-based conclusions could be reached due to the limited methodologic quality of available trials.
American Academy of Pediatrics

The American Academy of Pediatrics (AAP) (2011) revised its 2003 policy on the prevention and management of positional skull deformities in infants.\textsuperscript{29,30} The AAP indicated that in most cases, the diagnosis and successful management of deformational plagiocephaly can be assumed by the pediatrician or primary health care clinician and that mechanical methods, if performed early in life, may prevent further skull deformity and may reverse existing deformity. In most cases, an improvement is seen over a 2- to 3-month period with repositioning and neck exercises, especially if these measures are instituted as soon as the condition is recognized. The AAP indicated that use of helmets and 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.

In a policy statement, the AAP (2011) indicated that consideration should be given to early referral of infants with plagiocephaly when it is evident that conservative measures have been ineffective, because orthotic devices may help avoid the need for surgery in some cases.\textsuperscript{31} The AAP also recommended placing infants on their backs for sleep with supervised “tummy time” for the prevention of plagiocephaly.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Multiple cranial orthoses (helmets) have been cleared for marketing by the U.S. Food and Drug Administration 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 brachycephatic-shaped heads. Food and Drug Administration product code: MVA.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/08/15</td>
<td>New Policy. Adopting to support medical necessary indications; excluded in contract language. Policy effective date is May 1, 2016 following provider notification.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>04/20/16</td>
<td>Annual review. Policy updated with literature review. Coverage criteria expanded; assessment information moved from policy guidelines to policy section.</td>
</tr>
<tr>
<td>11/08/16</td>
<td>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).</td>
</tr>
<tr>
<td>02/01/17</td>
<td>Annual Review, approved January 10, 2017. Policy updated with literature review through September 26, 2016; no references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>03/24/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>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</td>
</tr>
<tr>
<td>09/01/18</td>
<td>Minor update. Re-added Consideration of Age information; it was inadvertently removed in a previous update.</td>
</tr>
<tr>
<td>10/01/19</td>
<td>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.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>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.</td>
</tr>
</tbody>
</table>

**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). ©2020 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.
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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Deutsche (German):

Hmoob (Hmong):

Illoko (Ilocano):
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