Cranial Orthotic Devices for Positional or Deformational Plagiocephaly

Coverage Policy

Coverage for External Prosthetics including cranial orthotic devices varies across plans. Please refer to the customer’s benefit plan document for coverage details.

Under many benefit plans, cranial orthotic devices are only covered when used postoperatively for synostotic plagiocephaly (premature closure of the skeletal sutures) and not for positional plagiocephaly (flattening of the head).

A custom molded/fitted cranial orthotic device (HCPCS code S1040) is considered medically necessary for the treatment of synostotic plagiocephaly (i.e., craniosynostosis) following surgical correction when the benefit plan includes coverage for this indication.

A custom molded/fitted cranial orthotic device (HCPCS code S1040) is considered medically necessary for the treatment of moderate to severe nonsynostotic positional plagiocephaly when the benefit plan includes coverage for this indication and ALL of the following conditions are met:

- Child is **EITHER ONE** of the following:
  - between three and five months of age and has failed to respond to a two-month trial of repositioning therapy
  - age six months to 18 months
Cranial asymmetry as evidenced by EITHER of the following:

- cephalic index ± at least two standard deviations from the mean for the appropriate gender/age (see Table 1)
- asymmetry of 12 mm or more in ONE of the following measures:
  - cranial vault
  - skull base
  - orbitotragial depth (see Table 2)

A subsequent custom molded/fitted cranial orthotic device to accommodate growth changes is considered medically necessary when significant cranial asymmetry persists and further meaningful improvement in the asymmetry is expected with continued use of a cranial orthotic device.

Custom molded/fitted cranial orthotic devices are considered not medically necessary for all other indications.

Replacement of a cranial orthotic device is considered not medically necessary if it becomes unusable or nonfunctioning because of misuse, abuse or neglect.

Please note that a protective helmet (HCPCS code A8000–A8004) is not a cranial remolding device. A protective helmet (HCPCS code A8000-A8004) is considered a safety device worn to prevent injury to the head rather than a device needed for active treatment, and is not considered medically necessary.

**Overview**

This Coverage Policy addresses cranial orthotic devices for the treatment of synostotic plagiocephaly (i.e., craniosynostosis) following surgical correction and nonsynostotic positional plagiocephaly (i.e., deformational plagiocephaly).

**General Background**

Cranial asymmetry may be caused by mechanical factors in-utero or after birth and can be classified as positional or nonpositional plagiocephaly. Plagiocephaly, also called flat head syndrome, is a flat spot on the back or side of a baby's head. Positional plagiocephaly, also called deformational plagiocephaly, results from external pressure (molding) that causes the skull to become misshapen. It is most often associated with infants sleeping or lying on their backs. Other conditions that may result in plagiocephaly include intrauterine molding (e.g., multiple gestation, large for gestational age, breech birth), birth trauma (e.g., forceps delivery, vacuum extraction), congenital torticollis, and prematurity (Laughlin, et al., 2011). If positional plagiocephaly is detected in early infancy, frequent repositioning of the infant’s head, combined with prone positioning during waking hours, can correct the condition in the majority of children. When external molding causes the entire back of the head to be flat, it is called positional brachycephaly. In the most severe cases of plagiocephaly, the head will take on a “windswept” or parallelogram appearance. If the cranial asymmetry is not detected early, or if repositioning therapy is unsuccessful, cranial orthotic devices may be used to mold the infant's skull back into the correct position. Surgical correction is rarely indicated for positional plagiocephaly.

The nonpositional causes of an abnormally shaped infant head include synostosis and hydrocephalus. Synostosis (i.e., craniosynostosis) occurs when one or more of the sutures in the infant's skull fuse prematurely. The premature fusion puts pressure on the brain, potentially restricting brain growth and exerting pressure on the other skull bones to expand out of proportion, leading to abnormal skull shape. Associated hydrocephalus may occur when two or more sutures are fused. The most common form of craniosynostosis, scaphocephaly (also called dolichocephaly), is a condition in which the head is abnormally long and narrow; it is often associated with an absent or small anterior fontanel. Calvarial vault reconstruction (i.e., cranial vault remodeling) and frontoorbital advancement are considered the mainstays of surgical treatment for craniosynostosis. Additional surgical treatment for craniosynostosis include endoscopic-assisted surgery (e.g., strip craniectomy, strip synostectomy) and bone distraction. Surgical technique varies among authors and is dependent on factors including the affected portions of calvaria and orbits, in addition to surgeon experience. A cranial orthotic device may be used
along with corrective surgery in the treatment of synostosis. Cranial remodeling helmets prevent recurrence of the
deformity and promote corrective reshaping. Cranial orthotic devices are contraindicated for the treatment of
hydrocephalus and prior to surgical correction of craniosynostosis. The devices have not been proven to prevent
or correct neurodevelopmental delay or disability.

Evaluation of Plagiocephaly

Cephalic Index: Evaluation of cranial asymmetry may be based on the cephalic index, a ratio between the width
(side to side) and length (front to back) of the head. Head width is calculated by subtracting the distance from the
euryon on the right side of the head (eur) to the euryon on the left side of head (eul) and multiplying by 100.
Head length is generally calculated by measuring the distance from the glabella midpoint (g) (midpoint of the flat
area of bone just above the nose between the eyebrows) to the opisthocranion point (op), the most projecting
point at the back of the head (posterior most point in the midsagittal plane of the occiput) (Figure A).

The cephalic index is then calculated as:

\[
\frac{\text{Head width (eu – eu)} \times 100}{\text{Head length (g – op)}}
\]

The cephalic index is considered abnormal if it is two standard deviations (SD) above or below the mean
measurements (American Academy of Orthotists and Prosthetists [AAOP], 2004; Farkas and Munro, 1987). The
indices for infants up to 12 months may be found on the following table:

<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>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>
</tbody>
</table>

Anthropometric Measurements: The evaluation of cranial asymmetry may also be made based on one or
more of three anthropometric measures: cranial vault, skull base or orbitotragial depth measurements (AAOP,
2004; Littlefield, et al., 1998). A physician or technician skilled in anthropometry should perform all
anthropometric measurements. Cranial orthoses have been indicated for moderate to severe plagiocephaly
defined as asymmetry of 12 mm or more (Moss, 1997). Table 2 below defines how these measurements are
taken and Figure 1 below illustrates some of the anthropometric landmarks.
<table>
<thead>
<tr>
<th>Cranial Vault</th>
<th>$\text{[left frontozygomatic point (fz) to right euryon (eu)]} - \text{[right frontozygomatic point (fz) to left euryon (eu)]}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skull Base</td>
<td>$\text{[subnasal point (sn) to left tragus (t)]} - \text{[subnasal point (sn) to right tragus (t)]}$</td>
</tr>
<tr>
<td>Orbitotragial Depth</td>
<td>$\text{[left exocanthion point (ex) to left tragus (t)]} - \text{[right exocanthion point (ex) to right tragus (t)]}$</td>
</tr>
</tbody>
</table>

**Figure 1. Anthropomorphic Landmarks**

( Hayden, Inc. 2014)

**Treatment for Positional Plagiocephaly**

Treatment for positional plagiocephaly is based on the age of the infant and the severity of the deformity. The optimal treatment is prevention through active counterpositioning of sleeping babies until they are able to move their heads freely during sleep, usually by six months of age. For positional plagiocephaly, primary treatment consisting of a trial of physical and positional therapy in infants under the age of six months is well-established. This type of therapy generally lasts two to three months and encourages normal neck mobility and relieves continued pressure on the affected area.

Infants for whom physical and positional therapy have failed or who are six months or older when the initial diagnosis of positional plagiocephaly is made, may require active reshaping of the skull through an external orthosis. The cranial orthosis is a custom molded helmet used to redirect growth of the skull bones and decrease cranial asymmetry. Casting or scanning methods that employ digital representation may be used to develop a representative model of the infant's head. Generally, a mold is made out of plastic that is slightly larger than the patient’s skull, it is then custom fitted with inserts to provide gentle pressure for reshaping. The best response to use of the helmet occurs at 4–12 months of age because of the greater malleability of infant skull bone and the normalizing effect of the rapid growth of infant brain tissue (Laughlin, et al., 2011). When the cranial helmet is used after 12 months of age, there is less improvement in the shape of the cranial structure (Laughlin, et al., 2011).

These devices may be dynamic, compressing the prominent part of the skull, or passive, allowing growth only in the flattened part of the skull. They are generally worn 15–22 hours a day, and length of treatment depends on the infant's age, the severity of the asymmetry, and compliance with the treatment regimen (AAOP, 2004; Loveday, et al., 2001; Littlefield, et al., 1998; Pollack, et al., 1997). On average, treatment programs for infants last 2–4 months and treatment programs for older children are of longer duration. Treatment is most effective when begun during the first year of life, when brain growth is most rapid (Kelly, et al., 1999; Loveday, et al., 2001; Marshall, et al., 1997; Pollack, et al., 1997). In some cases, where rapid growth and a need for continued correction make it necessary, a second band may be required (AAOP, 2004). Replacement depends on individual growth patterns and the expectation for continued significant improvement in cranial asymmetry.

Once cranial symmetry or improvement of the underlying presenting condition is achieved, treatment is generally discontinued. The point for which treatment is discontinued is not clearly established in the medical literature. Generally, discontinuation of treatment occurs at the discretion of the medical team and family. Minor asymmetry, or asymmetry so mild it would not require treatment, is considered within normal limits.

U.S. Food and Drug Administration (FDA)
Cranial orthoses are regulated by the FDA as Class II medical devices and require 510(k) approval. According to the FDA, these devices are intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly. Several orthoses have been FDA approved and include but are not limited to the following devices:

- Dynamic Orthotic Cranioplasty (DOC™) Band, Cranial Technologies, Inc. (Phoenix, AZ)
- Ballert Cranial Molding Helmet, Ballert Orthopedic (Chicago, IL)
- RHS Cranial Helmet, Restorative Health Services, Inc. (Nashville, TN)
- Hanger Cranial Band, Hanger Orthopedic Group, Inc. (Bethesda, MD)
- P.A.P. Orthosis (Plagiocephalic Applied Pressure Orthosis), Fit Well Prosthetic Orthotic Center (Personal Performance Medical) (Salt Lake City, UT).
- O & P Cranial Molding Helmet, Orthotic and Prosthetic Lab, Inc. (Evansville, IN)
- Cranial Solutions Orthosis CSO, Cranial Solutions (Pompton Lakes, NJ)
- Cranial Symmetry System, Beverly Hills Prosthetics Orthotics, Inc. (Los Angeles, CA)
- STARBand™, STARlight™ Cranial Remolding Orthosis, and the Clarren Helmet, Orthomerica Products, Inc. (Newport Beach, CA)
- ECA orthosis, Eastern Cranial Affiliates, Infinite Technologies (Arlington, VA)
- COPC Band, Center for Orthotic and Prosthetic Care of KY (Louisville, KY)

Literature Review
Evidence in the published peer-reviewed scientific literature suggests that cranial orthotic devices are proven effective in attaining correction of a more normal head shape in infants with positional plagiocephaly (Wilbrand, et al., 2016; Naidoo, et al., 2015; Steinberg, et al., 2015; Loveday, et al., 2001; Littlefield, et al., 1998; Moss, 1997; Pollack, et al., 1997; Littlefield, et al., 1997). Evidence evaluating cranial orthotic devices for positional plagiocephaly consists of prospective and retrospective case series and systematic reviews with few randomized clinical trials. Studies comparing one device to another are lacking. There is little clarity or agreement in the published medical literature regarding the criteria for initiating cranial orthotic therapy. Since slight variation in head shape and size are considered normal, the use of cranial orthoses should be selective and is indicated only where failure to treat would leave the child with an enduring abnormal appearance. Loveday et al. (2001) used a cranial index which represents the width of the head as a percent of the length of the head as criteria for treatment. Moss (1997) treated infants with moderate-to-severe plagiocephaly, defined as an asymmetry of 12 mm or more, with molding bands. Mulliken et al. (1999) described major cranial asymmetry as a difference of 12 to 10 mm. According to a systematic review (Xia, et al., 2008) repositioning therapy is preferred over molding therapy in patients who are age four months or less and in whom the severity of asymmetry is considered moderate or less. In patients who are age six months or older, or for whom the asymmetry is more than moderate (regardless of age) molding therapy is preferred. Several studies (Kelly, et al., 1999; Littlefield, et al., 1998; Marshall, et al., 1997; Pollack, et al., 1997) do not offer quantified criteria for initiation of treatment. The general consensus in the published literature is that the age at which treatment is initiated directly correlates with the length of treatment. Overall, the acceptable range of ages for treatment is three to 18 months.

While it has been suggested that there might be a correlation between deformational plagiocephaly and neurodevelopmental and other disorders, interpretation of data is not clear and further studies are necessary to establish a direct correlation. The AAP noted in a clinical report (Laughlin, et al., 2011) that although rigorous studies addressing the concern for developmental delay are lacking, there is no evidence to support that positional skull deformity results in developmental delays. Additionally the AAP noted that there has been no credible evidence to support a link to conditions such as mandibular asymmetry, otitis media, temporomandibular joint (TMJ) syndrome, developmental visual disorders, scoliosis or hip dislocation (Laughlin, et al., 2011). However, developmental screening and monitoring of infants with deformational plagiocephaly in order to evaluate the need for early intervention services has been suggested (Collett, et al; 2012).
Professional Societies/Organizations
The Congress of Neurological Surgeons (CNS) and the American Association of Neurological Surgeons (AANS)/CNS Joint Section on Pediatric Neurosurgery published 2016 guidelines for the treatment of pediatric positional plagiocephaly. Fifteen articles met inclusion criteria including one randomized controlled trial, five prospective comparative studies and nine retrospective comparative reviews. The Societies concluded that there is a fairly substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial shape in infants with positional plagiocephaly when helmet therapy is used as compared to conservative therapy. This is especially true if the deformity is severe and therapy is applied during the appropriate period of infancy. They also noted that specific criteria regarding the measurement and quantification of deformity and the most appropriate time window in infancy for helmet therapy “remain elusive”. Based on the review, infants with a more severe presenting deformity and infants who are helmeted early in infancy (e.g., before age eight months) tend to have more significant correction of head shape and even normalization. The recommendations stated that helmet therapy is recommended for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (e.g., repositioning, physical therapy) and for infants with moderate to severe plagiocephaly presenting at an advanced age (usually over eight months old).

According to a clinical report published by the American Academy of Pediatrics (Laughlin, et al., 2011; Persing, et al. 2003) regarding prevention and management of positional skull deformities in infants, management of deformational plagiocephaly includes preventive counseling for parents, mechanical adjustments, and exercises. Skull molding helmets may be considered an option for patients with severe deformity or skull shape that is refractory to physical adjustments and positioning. Surgery is rarely necessary but may be indicated for severe refractory cases of deformational plagiocephaly or in patients with craniosynostosis.

Use Outside of the US:
In the Canadian Pediatric Society Practice Points (2011; reaffirmed 2016) on positional plagiocephaly, the Society's recommendations stated that repositioning therapy plus physiotherapy as needed are the interventions of choice in most children with mild or moderate positional plagiocephaly. They also stated that moulding or helmet therapy may be considered for children with severe asymmetry. In these children, helmet therapy has been shown to influence the rate of improvement of asymmetry but not its final outcome. The evidence is insufficient to recommend helmet therapy for mild or moderate asymmetry.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Cranial Orthotic Device

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

<table>
<thead>
<tr>
<th>HCPCS Codes</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>

Protective Helmet

Considered a safety device and Not medically necessary:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A8000</td>
<td>Helmet, protective, soft, prefabricated, includes all components and accessories</td>
</tr>
<tr>
<td>A8001</td>
<td>Helmet, protective, hard, prefabricated, includes all components and accessories</td>
</tr>
<tr>
<td>A8002</td>
<td>Helmet, protective, soft, custom fabricated, includes all components and accessories</td>
</tr>
</tbody>
</table>
References


