Cigna Medical Coverage Policy

Subject **Cranial Orthotic Devices for Positional or Deformational Plagiocephaly**

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Coverage Policy

Coverage for cranial orthotic devices is generally subject to the terms, conditions and limitations of the External Prosthetic Appliance and Devices (EPA) benefit or Durable Medical Equipment (DME) benefit and schedule of copayments. In addition, some benefit plans may specifically exclude or limit coverage of cranial orthotic devices to certain indications. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for EPA and DME is limited to the lowest-cost alternative.

If coverage for a cranial orthotic device is available, the following conditions of coverage apply.

Cigna covers a custom molded/fitted cranial orthotic device (HCPCS code S1040) as medically necessary for the treatment of EITHER of the following conditions:

- synostotic plagiocephaly (i.e., craniosynostosis) following surgical correction
- moderate to severe nonsynostotic positional plagiocephaly, when **ALL** of the following conditions are met:
  - Photographic evidence supporting moderate to severe nonsynostotic positional plagiocephaly.
  - 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 of age
  - 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)

Cigna covers a subsequent custom molded/fitted cranial orthotic device to accommodate growth changes when medical necessity was previously established for the initial device, significant cranial asymmetry persists, and further meaningful improvement is expected with continued use of the cranial orthotic device.

Cigna does not cover replacement of a cranial orthotic device 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. Cigna does not cover a protective helmet (HCPCS code A8000-A8004) because it is considered a safety device worn to prevent injury to the head rather than a device needed for active treatment, and it is not considered medically necessary.

General Background

Cranial asymmetry may be caused by mechanical factors in-utero or after birth and can be classified as positional or nonpositional plagiocephaly. 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 it 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. If the skull appears abnormally long and narrow because of external molding, it is called positional scaphocephaly. 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 of one or more sutures 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 fronto-orbital advancement are considered the mainstays of surgical treatment for craniosynostosis. Additionally, recent advancements in surgical technique to treat 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 remolding 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.

Evaluation of Plagiocephaly
Cephalic Index: Evaluation of cranial asymmetry may be based on the cephalic index, a ratio between the width and length of the head. 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:

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

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 1
Cephalic Index

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
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

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.

Table 2
Specifications for Taking 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)]

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. Primary treatment consisting of a trial of physical and positional therapy in infants under the age of six months for positional plagiocephaly 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 infants 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.

Surgery for correction of positional plagiocephaly is rarely warranted (Marshall, et al., 1997; Pollack, et al., 1998, Xia, et al., 2008, Laughlin, et al., 2011).

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 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 FDA-approved orthoses are available 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
The published peer-reviewed scientific literature suggests that cranial orthotic devices are effective in attaining (Littlefield, et al., 1998; Loveday, et al., 2001; Moss, 1997; Pollack, et al., 1997) and maintaining (Littlefield, et al., 1997) a more normal head shape in infants with positional plagiocephaly, although studies comparing one device to another are lacking. Evidence evaluating cranial orthotic devices for positional plagiocephaly consists of case series and systematic reviews. There is little clarity or agreement in the published medical literature as to the criteria for initiating cranial orthotic therapy. Wood (2000) suggests that, 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) use 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) describe 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. Nonetheless, 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 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 notes 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
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: No relevant information.

Summary
When repositioning therapy has been unsuccessful for moderate to severe plagiocephaly, custom molded/fitted cranial orthotic devices have been proven in the published, peer-reviewed scientific literature to be safe and effective for reducing skull asymmetry. There is also evidence in the literature that cranial orthotic devices prevent recurrence of the deformity and promote corrective reshaping following surgical repair of craniosynostosis.

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.
3) ICD-10-CM Diagnosis Codes are for informational purposes only and are not effective until 10/01/2014.

Cranial Orthotic Device

Covered when medically necessary:

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

Protective Helmet

Safety device/Not medically necessary/Not covered:

HCPCS Codes	Description
A8000	Helmet, protective, soft, prefabricated, includes all components and accessories
A8001	Helmet, protective, hard, prefabricated, includes all components and accessories
A8002	Helmet, protective, soft, custom fabricated, includes all components and

	accessories
A8003	Helmet, protective, hard, custom fabricated, includes all components and accessories
A8004	Soft interface for helmet, replacement only

***Current Procedural Terminology (CPT®) ©2013 American Medical Association: Chicago, IL.**

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