Adjustable Cranial Orthoses for Positional Plagiocephaly and Craniosynostoses*

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DESCRIPTION

Note: *This medical policy does not address the following: protective helmet (HCPCS codes A8000–A8004) or (HCPCS codes L0112 or L0113) cranial cervical orthosis for the treatment of torticollis, see Policy Guideline section below for additional information related to these orthoses.*

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.

The skull consists of several plates of bone that are separated by sutures. As a child grows and develops, the sutures close, forming a solid piece of bone called the cranium. Sometimes the bones fuse incorrectly, resulting in cranial asymmetry; however, abnormalities in head shape (i.e., cranial asymmetry) may develop due to a variety of factors. Plagiocephaly is generally defined as cranial asymmetry and can be subdivided into two types: synostotic and nonsynostotic.

Synostotic Plagiocephaly

In synostotic plagiocephaly or craniosynostosis, premature fusing of one or more sutures in a child's cranium restricts skull and brain growth. This may cause increased pressure inside the head and/or cause the cranial or facial bones to be asymmetrical. 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. The diagnosis of synostotic plagiocephaly is made after a clinical evaluation and diagnostic testing. Surgery is typically the recommended treatment involving the surgical remodeling of the cranial vault. Cranial remolding orthoses (helmets) may be used for adjunctive postsurgical therapy. The goal of treatment is to reduce the pressure in the head and to correct the deformities of the face and skull bones. The ideal timing for this type of surgery is prior to 3 months of age. However, there is no upper age limit to surgery, and in some instances, children may need minor surgical follow-up at 4 to 5 years of age.

Nonsynostotic Plagiocephaly

Nonsynostotic plagiocephaly, also called positional or deformational plagiocephaly, the sutures of the cranium remain open (usually up to 12 months of age). The asymmetry 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. Most of these deformities may auto-correct spontaneously during the first few months of life 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.

Cranial Asymmetry

An objective evaluation of cranial asymmetry may be based on anthropometric landmarks and/or the cephalic index. Anthropometric measurements of the cranial vault, cranial base, and orbitotragial depth help to identify asymmetries by evaluating the length

from one designated point on the face or cranium to another and comparing right and left sides. The degree of asymmetry also may be assessed by a comparison with normative values using the cephalic index. The cephalic index is the ratio of the maximum width of the cranium to its maximum length multiplied by 100. Additionally, the clinical evaluation of cranial asymmetry is useful to orthotists for fabricating cranial remolding orthoses (helmets) and in documenting treatment outcomes.

Cranial Remolding Orthoses – Helmets
A cranial remolding orthosis - helmet, sometimes referred to as a cranial band or dynamic orthotic cranioplasty (DOC), is a noninvasive custom-molded orthotic device that applies pressure to prominent regions of the cranium to progressively improve cranial shape and symmetry. The custom-molded orthotic is designed to be worn 23 hours a day with an hour off for exercise and skin care. The headband or helmet is initiated between three and 18 months of age and is worn for an average of two to four months. Adjustments to the helmet need to be made every one to two weeks because a baby's head grows very quickly. This involves adjusting the foam lining and/or portions of the outside plastic helmet.

Cranial remolding bands and helmets are contraindicated in infants older than 24 months. The skull of these children has finished growing and no longer have the pliability and plasticity necessary to create a change in shape.

Cranial Orthoses for Synostotic Plagiocephaly (Craniosynostosis)

Clinical Context and Therapy Purpose
The purpose of postoperative cranial orthosis is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as cranial vault remodeling without a cranial orthosis, in patients with open or endoscopic surgery for craniosynostosis.

Populations
The relevant population of interest is individuals with open or endoscopic surgery for craniosynostosis.

Interventions
The therapy being considered is postoperative cranial orthosis.

Comparators
Comparators of interest include cranial vault remodeling without a cranial orthosis. Treatments for craniosynostosis include surgeries such as strip sagittal craniectomy, frontal-orbital advancement, and frontal-occipital reversal.

Outcomes
The general outcomes of interest are a change in disease status, morbid events, functional outcomes, quality of life (QOL), and treatment-related morbidity. The existing literature

evaluating postoperative cranial orthosis as a treatment for open or endoscopic surgery for craniosynostosis has varying lengths of follow-up, ranging from 13 to 25 months. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 12 to 24 months of follow-up is considered appropriate to demonstrate efficacy. Patients with open or endoscopic surgery for craniosynostosis are actively managed by neurosurgeons, plastic surgeons, and primary care providers in an inpatient clinical setting.

Literature Review

Early literature consisted of a few case series that described the use of cranial orthoses following either open or endoscopically assisted surgery for craniosynostosis, which included the following:

- The orthoses improved Cephalic Index score (100 times the ratio of cranial biparietal diameter and occipitofrontal diameter) more than a similar type of surgery without an orthosis reported elsewhere.
- The Cephalic Index score improved by 4 (range, 67-71) from baseline to 1 year in studies using surgery alone but improved by 10 (range, 65-75) with combined treatment (Cephalic Index normal range, 75-90).
- Anthropomorphic measurements at 3, 6, 9, and 12 months after surgery showed continued improvement in symmetry in most patients.
- The decision to discontinue therapy was based on the child reaching the 12-month postoperative mark or 18 months of age. After the first year post surgery, patients were followed annually or biannually (range, 3-135 months). The mean preoperative Cephalic Index score was 98. The postoperative Cephalic Index score (>1 year) was 83, a 15% decrease from baseline.

Since these initial reports, literature updates have identified a larger series describing endoscopically assisted strip craniectomy and postoperative helmet therapy for craniosynostosis, which included the following:

- Because head-shape correction occurs slowly after surgery, helmet therapy is as important as the surgery to remove the abnormal suture.
- Outcomes from endoscopically assisted versus open repair of sagittal craniosynostosis. The endoscopic procedure was offered starting in 2006 and has become the most commonly performed approach. The 42 patients treated with open-vault reconstruction had a mean age at surgery of 6.8 months and a mean follow-up of 25 months. Mean age of the 47 endoscopically treated patients at surgery was 3.6 months and a mean follow-up was 13 months. Of the 29 endoscopically treated patients who completed helmet therapy, the mean duration for helmet therapy was 8.7 months.

Summary of Evidence

The evidence on the efficacy of cranial orthoses (remolding helmet or band) following endoscopically assisted or open cranial vault remodeling surgery for synostotic plagiocephaly (craniosynostosis) is limited and includes only case series. In the postoperative period after craniosynostosis repair, the role of cranial orthoses is to

continue remodeling the skull after surgery. Functional impairments are related to craniosynostosis, including the potential for increased intracranial pressure and the risk of harm from additional surgery when severe deformity has not been corrected. This indirect evidence that cranial orthoses (remolding helmet or band) can facilitate remodeling, and the use of a cranial orthosis is likely to improve outcomes after cranial vault remodeling for synostosis is considered sufficient to suggest an improvement in health outcomes with postsurgical use of cranial orthosis (remolding helmet or band) for synostotic plagiocephaly (craniosynostosis).

Cranial Orthoses for Nonsynostotic Plagiocephaly (Positional Plagiocephaly)

Clinical Context and Therapy Purpose
The purpose of cranial orthosis is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as positioning therapy, in patients with positional plagiocephaly.

Populations
The relevant population of interest is individuals with positional plagiocephaly. Some increase in the prevalence of positional plagiocephaly may be related to the change in recommended sleep practice (back to sleep) to prevent sudden infant death syndrome.

Interventions
The therapy being considered is cranial orthosis. Custom-fitted cranial orthoses are designed to be worn 23 hours a day for several months.

Comparators
Comparators of interest include positioning therapy. Treatment for positional plagiocephaly includes head repositioning and helmet therapy. 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.

Outcomes
The general outcomes of interest are a change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Guideline-related systematic reviews reported a mean duration of cranial orthotic as 4 - 6 months depending on the age of the patient with longer-term outcome assessments reported at 2 years. Patients with positional plagiocephaly are managed by neurologists, pediatricians and other primary care providers in an outpatient clinical setting.

Literature Review
Picart et. al. 2020, reported on the results of a retrospective systematic review of cranial helmet therapy for positional cranial deformation. The review included 2188 children with positional cranial deformation with a median age of 8 months 4 days. The endpoints

to determine the effectiveness of cranial helmet therapy included restoration of facial symmetry (successful treatment), requirement of posterior cranial remodeling (treatment failure), significant decrease of the cranial index (successful treatment of brachycephaly), and significant decrease in cranial diagonals difference (CDD). Facial symmetry was considered restored when the left and right distances from the tragus to the lateral canthus and to the corner of the mouth were equal. A total of 13.7% of children had facial symmetry at the beginning of treatment, and after helmet therapy the total improved to 66.7% ($p<0.01$). Children with cranial indexes > 80% were diagnosed with brachycephaly. The cranial index prior to helmet therapy ranged from an average of $103.5 \pm 6\%$, and with therapy improved to $96.7 \pm 7.2\%$ ($p<0.01$). Children in the unilateral deformity subgroup had a mean CDD of 1.50 ± 0.54 cm and post therapy measurements improved to 0.72 ± 0.37. This review was a single center, retrospective review that lacked a control group. A prospective multicenter study that follows children throughout their development into adolescence is needed to validate broader and more lasting applicability of these results.

Kunz, et. al. in 2019, investigated the long-term outcomes of head orthosis therapy for deformational plagiocephaly in a prospective, longitudinal study. The researchers defined deformational plagiocephaly as a CVAI of more than 3.5%. A total of 63 infants were divided into three groups: one group treated with a head orthosis (n=32), one group treated without a head orthosis (n=13), and one control group without visible head asymmetries and a CVAI ≤ 3.5% (n=18). After 3D-stereophotogrammetric imaging and consultation, the infants were allocated to the "treated" or "untreated" group depending on the parents' decision. The treatment group had regular check-ups and readjustments every 4-5 weeks until a satisfactory head shape was achieved. When the participants were 4 years old, they had a follow-up assessment and 3D scan. The researchers found that reduction in asymmetry for the treated group was significantly higher for the CVAI and posterior cranial asymmetry index (PCAI). The maximum opening of the mouth was similar between the two groups. The study was limited by a small sample size and single-center location.

Mackel et. al. in 2017, explored whether cranial helmet therapy initiated before 6 months of age leads to reduced plagiocephaly. The authors retrospectively reviewed the records of 45 infants (age range 3-11 months) who underwent cranial helmet therapy between 2010 and 2015. A total of 21 subjects were < 6 months old at the start of helmet therapy. The CVAI was significantly smaller at the beginning and end of therapy at < 6 months compared to subjects who began therapy after 6 months (7.4 ± 2.9 vs. $9.4 \pm 2.1\%$, $p=0.01$; 4.5 ± 2.8 vs. $6.4 \pm 2.3\%$, $p=0.015$). The reduction in CVAI did not significantly vary between groups. The researchers found that an increase in either initial CVAI or age at the initiation of treatment correlated with the final CVAI, but length of helmet wear did not correlate with final CVAI. The authors stated that "among infants who started helmet wear at 4–8 months of age, those who began helmet wear at 6–8 months achieved a similar cranial symmetry in comparison to patients who initiated helmet wear at 4–5 months." The study was limited by retrospective design, small sample size, and single-center location.

Han et. al. in 2017, studied the relationship between the starting age of cranial orthotic therapy and effectiveness of treatment in infants with deformational plagiocephaly. The authors retrospectively analyzed the records of 310 infants who underwent cranial-remolding-orthosis therapy between 2010 and 2016. Subjects were categorized by severity of initial plagiocephaly (mild, moderate, and severe) and initiation age (3 months to 9 months). The mean CVAI was the greatest in the 3-month group (10.4 to 3.5%) and shortest in the 9- month group (9.8 to 5.7%). The mean CVAI was significantly lower for the 6–9-month groups than the 3-month group; however, there was not a significant change between the 3–5-month groups. The mean CVAI improvement rate was highest in the 3-month group (67.9%) and lowest in the 9-month group (43.4%). The mean duration of cranial-remolding-orthosis therapy was shortest in the 3-month group (124 days) and longest in the 8-month group (222 days). The authors concluded that starting cranial-remolding-orthosis therapy after 6 months is associated with a longer duration of treatment and decreased rates of CVAI improvement. They found that 5 months was the most optimal age to start treatment for deformational plagiocephaly. The study was limited by the retrospective design, uneven sample size for the different age groups, and lack of strict criteria for treatment termination.

In 2016, the Congress of Neurological Surgeons commissioned a systematic review to inform a joint evidence-based guideline on the role of cranial molding orthosis therapy for patients with positional plagiocephaly. 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). This systematic review concluded there is a substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial shape in infants with positional plagiocephaly treated with a helmet as compared to conservative therapy, especially if the deformity is severe, and provided that helmet therapy is applied during the appropriate period of infancy. Specific criteria regarding the measurement and quantification of deformity and the most appropriate time window in infancy for treatment of positional plagiocephaly with a helmet remain elusive. In general, infants with a more severe presenting deformity and infants who are helmeted early in infancy tend to have more significant correction (and even normalization) of head shape.

Summary of Evidence

For individuals who have nonsynostotic plagiocephaly **(**positional plagiocephaly) who receive a cranial orthoses (remolding helmet or band), the overall, evidence on an association between positional plagiocephaly and health outcomes is limited. A systematic review completed in 2016 by the Congress of Neurological Surgeons concluded there is a substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial shape in infants with positional plagiocephaly treated with a helmet as compared to conservative therapy, especially if the

deformity is severe, and provided that helmet therapy is applied during the appropriate period of infancy. 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, however, the evidence limitations are acknowledged. Medical organization guidelines have supported use of orthoses for positional plagiocephaly with criteria, the use of cranial orthoses will be considered medically necessary for certain conditions *(see Policy Criteria section below)*.

The use of adjustable cranial orthoses (remolding helmet or band) are contraindicated in infants older than 24 months as the skull of these children has finished growing and no longer have the pliability and plasticity necessary to create a change in shape.

Practice Guidelines and Position Statements

American Academy of Pediatrics (AAP)
In 2011, the American Academy of Pediatrics (AAP) revised its 2003 policy on the prevention and management of positional skull deformity in infants. 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, 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. *(This policy was retired in 2018)*

Congress of Neurological Surgeons
In 2016, the Congress of Neurological Surgeons commissioned a systematic review to inform a joint evidence-based guideline on the role of cranial molding orthosis therapy for patients with positional plagiocephaly. 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).

This guideline provided the following recommendations:

1. Physical examination is recommended for diagnosis of plagiocephaly with imaging necessary only rarely (Level III)

2. Physical therapy is recommended rather than positioning pillows (which cause a less safe sleeping environment), and more effective than repositioning education based on evidence from 1 Class-1 study.

3. Helmet therapy is recommended for infants with persistent moderate to severe plagiocephaly despite conservative therapy (Level II).

4. Helmet therapy is recommended for infants presenting at an advanced age with moderate to severe plagiocephaly (Level II).

These guidelines catalog the current state of the scientific literature regarding plagiocephaly, but also highlight the lack of high-grade evidence to guide clinical practice.

This systematic review concluded there is a substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial shape in infants with positional plagiocephaly treated with a helmet as compared to conservative therapy, especially if the deformity is severe, and provided that helmet therapy is applied during the appropriate period of infancy. Specific criteria regarding the measurement and quantification of deformity and the most appropriate time window in infancy for treatment of positional plagiocephaly with a helmet remain elusive. In general, infants with a more severe presenting deformity and infants who are helmeted early in infancy tend to have more significant correction (and even normalization) of head shape.

National Institute of Neurological Disorders and Stroke (NINDS)
In 2019, the National Institute of Neurological Disorders and Stroke (NINDS) stated the following: "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. For some children with less severe problems, cranial molds can reshape the skull to accommodate brain growth and improve the appearance of the head."

Regulatory Status
Cranial orthoses are classified by the FDA as Class II devices. This classification requires special controls, including prescription use, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, and instructions for physicians and parents). They 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, including infants with plagiocephalic-, brachycephalic-, and scaphocephalicshaped heads. The FDA has approved a large number of cranial orthoses.

PRIOR APPROVAL

Prior approval required.

POLICY

Note: *This medical policy does not address the following: protective helmet (HCPCS codes A8000–A8004) or (HCPCS codes L0112 or L0113) cranial cervical orthosis for*

the treatment of torticollis, see Policy Guideline section below for additional information related to these orthoses.

Cranial Orthoses (Remolding Helmet or Banding) for Synostotic Plagiocephaly (Craniosynostosis)

The use of adjustable cranial orthoses (remolding helmet or band) may be considered **medically necessary** in the post-operative management of infants following endoscopic repair of craniosynostosis.

The use of adjustable cranial orthoses (remolding helmet or band) may be considered **medically necessary** as an adjunct to surgical treatment of synostotic skull deformity of infants.

The use of adjustable cranial orthoses (remolding helmet or band) is considered **not medically necessary** when criteria above have not been met because the available published peer-reviewed literature does not support their use in the treatment of other illness or injury.

Cranial Orthoses (Remolding Helmet or Banding) for Nonsynostotic Plagiocephaly (Positional Plagiocephaly)

The use of adjustable cranial orthoses (remolding helmet or band) may be considered **medically necessary** when a diagnosis of moderate to severe nonsynostotic plagiocephaly (positional plagiocephaly) has been documented, and **ALL** of the following criteria are met:

- The infant is 3 to 18 months of age; **and**
- The infant has not responded to a two-month trial (8-weeks) of home management with head repositioning or other conservative therapies (i.e., physical therapy), unless such therapies are contraindicated or considered inappropriate due to other comorbidities; **and**
- Moderate to severe cranial asymmetry is documented by either of the following:
    - Moderate to severe plagiocephaly in ONE of the following anthropometric dimensions *(see Policy Guideline below)*:
        - Cranial vault
        - Cranial base
        - Orbitotragial depth; **or**
    - Cephalic index measurement at least two standard deviations above or below the mean for the appropriate gender and age *(see Policy Guideline below)*.

Subsequent (Replacement) Cranial Orthoses (Remolding Helmet or Banding)
A subsequent (replacement) adjustable cranial orthosis (remolding helmet or band) may be considered **medically necessary** when **ALL** of the following criteria are met:

- The medical necessity criteria outlined above is met; **and**

- The cranial asymmetry has not resolved or improved after two to four months *(Compliance is considered: 23 hours a day with an hour off for exercise and skin care unless documentation supports contraindicated or considered inappropriate due to other comorbidities)*; **and**
- There is a change in the infant's condition that requires a replacement adjustable cranial orthosis (remolding helmet or band) (e.g., growth [outgrown]) the initial orthoses, or haven't developed midline head control, rolling, or sitting).

Note: *Under normal circumstances, an infant's weight may triple in size between birth and 9 months. This significant growth rate is reflected by a concomitant and proportional increase in cranial size that may result in an improperly fitting or ineffective cranial orthoses.*

The use of adjustable cranial orthoses (remolding helmet or band) is considered **not medically necessary** when criteria above have not been met because the available because the available published peer-reviewed literature does not support their use in the treatment of other illness or injury.

The use of adjustable cranial orthoses (remolding helmet or band) is considered **not medically necessary** as they are contraindicated in infants older than 24 months as the skull of these children has finished growing and no longer have the pliability and plasticity necessary to create a change in shape.

Policy Guidelines

Notes:

- *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 managed by this medical policy, refer to the members benefit document for coverage and limitations.*
- *The following codes are not managed by this medical policy and prior approval is not applicable. The below codes would be utilized when the individual needs treatment for congenital torticollis and coverage would be subject to the members applicable benefits, refer to the members benefit document for coverage and limitations:*
    - *L0112 cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated (would be utilized if treating plagiocephaly and torticollis)*
    - *L0113 cranial cervical orthosis, torticollis type, with or without joint, with or without soft interface material, prefabricated includes fitting and adjustment (would be utilized for the treatment of torticollis only)*

Required Documentation
The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage and does not guarantee coverage of the service requested, submit medical notes documenting **ALL** of the following:

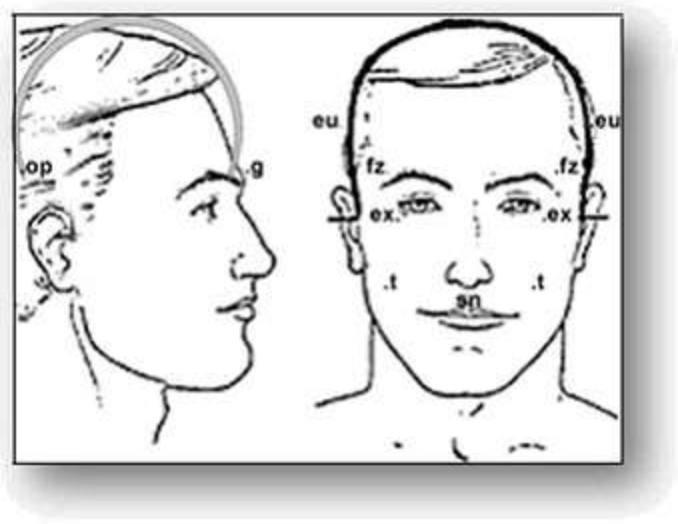
- Reason for orthotic
- Diagnosis
- Physical exam related to support the need of the orthotic; include neurological, circulatory, skin, and musculoskeletal examination that supports the request, as well as the presence or absence of torticollis
- At least one of the following:
    - Cranial vault asymmetry index (CVAI)
    - Cephalic index (CI)
    - Transcranial diameter difference (TDD)
    - Cranial vault asymmetry (CVA)
- Documentation of treatments tried, failed, contraindicated; include the dates and reason for discontinuing, including:
    - Repositioning
    - Physical or occupational therapy
- Orthotist notes to include the following:
    - Equipment quotes with billing codes
    - Reason for orthotic
    - Anthropometric Measurements
- Physician treatment plan, including plan to treat torticollis with cranial orthosis.

Replacement Requests

- In addition to the above documentation, also provide the following for a replacement request:
    - Age of current orthotic
    - Reason for replacement
    - Adjustments/modifications

ANTHROPOMETRIC DIMENSIONS

	Comparative Cranial Landmarks
Cranial Vault	Left frontozygomatic point (fz) to right euryon (eu) minus right frontozygomatic point (fz) to left euron (eu)
Cranial 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)



Moderate to severe plagiocephaly is defined as one of the following:
Cranial base (sn – t): >= 6 mm difference between left and right measurements
Cranial vault (fz – contralateral eu): >= 8 mm difference between left and right measurements
Obitotragial depth (ex – t): >= 4 mm difference between left and right measurements

CEPHALIC INDEX MEASUREMENT

CEPHALIC INDEX: $\frac{\text{Head width (eu — eu)}}{\text{Head length (g — op)}} \times 100$

(Cephalic index equal to head width eu minus eu multiplied by 100 divided by head length g minus op)

Moderate to severe plagiocephaly is defined as a cephalic index two standard deviations above or below the mean. Infants with deformational scaphocephaly will have a lower cephalic index due to a very long and narrow skull deformity. Infants with deformational brachycephaly will have an increased cephalic index due to a very wide and short skull deformity.

Gender	**Age**	**-2SD**	**-1SD**	**Mean**	**+1SD**	**+2SD**
Male	16 days – 6 months	63.7	68.7	73.7	78.7	83.7
	6-12 months	64.8	64.8	78	84.6	91.2

Female	16 days – 6 months	63.9	63.9	73.3	78	82.7
	6-12 months	69.5	69.5	78.5	83	87.5

Definitions

Asymmetry of cranial base: Asymmetry of the cranial base measured from the subnasal point (midline under the nose) to the tragus (the cartilaginous projection in front of the external auditory canal).

Asymmetry of cranial vault: The difference of the diagonal measurement 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 two diagonals are measured 30 degrees clockwise and counterclockwise from the mid-sagittal line.

Asymmetry of orbitotragial depth: An asymmetry of the orbitotragial depth that 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).

Brachiocephaly: A condition characterized by a head shape that is symmetric and disproportionately wide, (width ÷ length x 100%) ≥ 81%. This may be caused by abnormal growth rates of the skull bone plates or may be due to an infant being placed in the same position for prolonged periods of time. The latter is referred to as "positional brachycephaly."

Cranial base: Asymmetry of the cranial base is measured from the sub-nasal point (midline under the nose) to the tragus (the cartilaginous projection in front of the external auditory canal.

Cephalic index: Cephalic index (CI): The measurement of head width divided by head length then multiplied by one hundred and expressed as a percentage. CI 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 (also known as the euryon). The head length is measured from the most prominent point in the median sagittal plane between the supraorbital ridges (also called the glabella) to the most prominent posterior point of the occiput (that is, the ophisthocranion). The cephalic index can then be compared to normative measures. (0-3 months old: 75-95%, 4-6 months old: 74-94%, 7-12 months old: 73-93%, 13-18 months old: 72-92%).

Cranial Vault Asymmetry Index (CVAI): The percentage difference between the oblique measurements taken from 30˚ from vertical, or the absolute value of the

difference in cranial diagonals divided by the greater diagonal and multiplied by 100. (Abnormal: >3.5%).

Craniproportional Index of Plagiocephelometry: The ratio between the width (sinistra-dextra) and the length (anterior-posterior) of the skull multiplied by 100. This measurement provides the degree of brachycephalic component of deformation. (Mild 90-94%, Moderate 95-99%, Severe: ≥ 100%).

Craniosynostosis: A congenital deformity of the infant skull that occurs when the fibrous joints between the bones of the skull (called cranial sutures) close prematurely.

Non-synostotic Plagiocephaly: A condition where an infant's head becomes deformed due to external forces. In non-synostotic plagiocephaly, the joints between the skull bone plates (sutures) remain open, allowing non-surgical correction. This condition is also known as positional plagiocephaly.

Oblique Diameter Difference Index: The ratio between the longest cranial diagonal and the shortest cranial diagonal multiplied by 100. The diagonals are 40˚ from the anterior-posterior line. This measurement provides the degree of plagiocephalic component of deformation. (Mild: 104-107%, Moderate: 108-111%, Severe: ≥ 112%).

Orthotic Cranioplasty: A method to correct non-synostotic plagiocephaly through the wearing of a custom-fitted helmet or head band which places constant gentle pressure on the infant's head to assume a more natural skull shape.

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.

Scaphocephaly: A condition characterized by a head shape that is symmetric and disproportionately narrow. May be caused by abnormal growth rates of the skull bone plates or may be due to an infant being placed in the same position for prolonged periods of time.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- S1040 Cranial molding orthosis, rigid, with soft interface material, custom fabricated, includes fitting and adjustments.

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POLICY HISTORY

Date	Reason	Action
May 2022	Interim Review	Policy Revised
March 2022	Annual Review	Policy Revised
March 2021	Annual Review	Policy Renewed
January 2021	Interim Review	Policy Revised
March 2020	Annual Review	Policy Revised
March 2019	Annual Review	Policy Revised
March 2018	Annual Review	Policy Revised
March 2017	Annual Review	Policy Renewed
March 2016	Annual Review	Policy Revised
April 2015	Annual Review	Policy Renewed
May 2014	Annual Review	Policy Revised

July 2013	Annual Review	Policy Renewed
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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Des Moines, IA 50306-9232

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