Anthem

Clinical UM Guideline

Subject: Cranial Remodeling Bands and Helmets (Cranial Orthotics)
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Description

This document addresses the use of the adjustable band or helmet cranial orthoses as a treatment of craniosynostosis, non-synostotic plagiocephaly (asymmetrically shaped posterior head), scaphocephaly (abnormally shaped narrow head), and brachycephaly (abnormally shaped head; shortened in antero-posterior dimension without asymmetry) in infants.

Cosmetic: In this document, procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those which are primarily intended to preserve or improve appearance.

Medically Necessary: In this document, procedures are considered medically necessary if there is a significant functional impairment AND the procedure can be reasonably expected to improve the functional impairment.

Reconstructive: In this document, 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.

Note: Not all benefit contracts include benefits for reconstructive services as defined by this document. Benefit language supersedes this document.

Clinical Indications

Medically Necessary:

The use of an adjustable cranial orthosis is considered **medically necessary** in the post-operative management of infants following endoscopic repair of craniosynostosis.

The use of cranial orthoses is considered **medically necessary** as an adjunct to surgical treatment of synostotic skull deformity.

Reconstructive:

I. The initial use of cranial orthoses is considered **reconstructive** to treat non-synostotic skull deformity (including plagiocephaly, scaphocephaly, and brachycephaly) when the individual meets ALL the following criteria (A and B and C):
   A. The infant is at least three (3) months of age but not greater than twelve (12) months of age; **and**
   B. Documented failure of at least two (2) months of conservative therapy which includes either (1) or (2) below:
      1. Two (2) months of physical therapy for infants with associated cervical motion restriction, including initial and final assessment of range of motion; **or**
      2. Two (2) months of home management with repositioning for infants without cervical motion restriction; **and**
   C. Anthropomorphic measurements (see Definitions section) following conservative management with final measurements indicating ONE of the following:
      1. Cephalic index measurement is ONE of the following:
         a. 0-3 months of age: less than 75% or greater than 95%; **or**
         b. 4-6 months of age: less than 74% or greater than 94%; **or**
         c. 7-12 months of age: less than 73% or greater than 93%; **or**
      2. Cranial vault asymmetry index greater than 3.5%; **or**
      3. Oblique diameter difference index greater than 108%; **or**
      4. Craniproportional index of plagiocephelometry greater than 95%.

II. A second application of the cranial orthosis is considered **reconstructive** for infants between six (6) and eighteen (18) months of age when all the following criteria (A and B and C) have been met:
   A. Final post-therapy anthropomorphic measurements (see Definitions section) indicating ONE or more of the following:
      1. Cephalic index measurement is ONE of the following:
         a. 4-6 months of age: less than 74% or greater than 94%; **or**
         b. 7-12 months of age: less than 73% or greater than 93%; **or**
         c. 13-18 months of age: less than 72% or greater than 92% **or**
      2. Cranial vault asymmetry index greater than 3.5%; **or**
      3. Oblique diameter difference index greater than 108%; **or**
      4. Craniproportional index of plagiocephelometry greater than 95%; **and**
   B. One of the following (1 or 2):
      1. For infants with associated cervical motion restriction, documentation of physical therapy or home exercise program with interval assessment of range of motion since the initial orthotic application; **or**
      2. For infants without cervical motion restriction, at least two (2) months of home management with repositioning either before or after the initial application; **and**
   C. If a new orthosis is being requested, documentation of skin complications or inadequate therapeutic positioning due to head growth that cannot be managed or prevented with refitting of the original orthosis, when continued improvement is anticipated.

Not Medically Necessary:

The use of cranial orthoses is considered **not medically necessary** when criteria have not been met.

Initial application of cranial orthosis for infants over the age of twelve (12) months is considered **not medically necessary.**

Continued use of cranial orthosis after eighteen (18) months of age is considered **not medically necessary.**

Cosmetic and Not Medically Necessary:

The use of cranial orthoses is considered **cosmetic and not medically necessary** for non-surgical treatment of synostotic skull deformities.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary or Reconstructive when criteria are met:

HCPCS	
L0112	Cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

ICD-10 Diagnosis	
P13.0	Fracture of skull due to birth injury
P15.2	Sternomastoid injury due to birth injury
Q67.3	Plagiocephaly
Q67.4	Other congenital deformities of skull, face and jaw
Q68.0	Congenital deformity of sternocleidomastoid muscle (congenital torticollis)
Q75.001-Q75.08	Craniosynostosis
Q75.9	Congenital malformation of skull and face bones, unspecified

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a situation designated in the Clinical Indications section as not medically necessary.

When services are Cosmetic and Not Medically Necessary:
For the procedure codes listed above, when the code describes a procedure designated in the Clinical Indications section as cosmetic and not medically necessary (nonsurgical treatment).

Discussion/General Information

Craniosynostosis

Plagiocephaly, which refers to an asymmetrically shaped head, can be subdivided into synostotic and non-synostotic types. Synostotic plagiocephaly, or craniosynostosis, describes an asymmetrically shaped head due to premature closure of the sutures of the cranium. Craniosynostosis may require surgery to reopen the closed sutures. Surgery can be performed by an open or endoscopic technique, depending upon the type and extent of the synostosis.

The open approach requires an incision and may involve removing, reshaping, or replacing the deformed cranial bone. For this extensive surgery, dissolving plates and screws are used to maintain the reshaped cranium post operatively. In a review of surgical approaches for craniosynostosis, Mehta and colleagues (2010) addressed open procedures where complex calvarial vault remodeling was required for immediate deformity correction to prevent impending neurological dysfunction. Since cranial shape correction was accomplished with the surgery, a postoperative helmet was not required.

Seymour-Dempsey and colleagues (2002) evaluated the used of cranial orthotics and compared the operative outcomes of infants treated with and without cranial banding following surgery for craniosynostosis. This small, nonrandomized, retrospective study included 21 children with sagittal craniosynostosis treated surgically between 1994 and 2001. A total of 6 infants were treated with surgery alone and 15 were treated with surgery and postoperative cranial banding with the Dynamic Orthotic Cranioplasty® band (DOC band; Cranial Technologies, Inc. Phoenix, Arizona). The investigators recorded anthropomorphic measurements pre-operatively, post-surgery, and post-orthotic treatment. They found that the postoperative cephalic index, when compared with preoperative cephalic index, improved in both groups. While surgical improvement was seen in both groups, the orthotic group demonstrated a continued correction toward a more normal cephalic index not seen in the non-orthotic group. The authors concluded that the use of an orthosis maintains the initial surgical correction and promotes more normal cranial growth patterns. Based on this small, retrospective analysis, the authors recommend the use of cranial orthoses as an adjunct to surgery for sagittal synostosis.

Kaufman and colleagues (2004) reported a small (n=12) case series comparing outcomes of an open craniectomy for sagittal synostosis utilizing a postoperative cranial orthotic. In this group, immediate and 1 year postoperative CTs did not reveal a statistically significant improvement in cephalic index (preoperative cephalic index, 65 ± 3.4; range, 58 to 70; post-treatment cephalic index, 74 ± 4.3; range, 68 to 80). However, visually, the head shape was improved. The results of this study yielded similar results when compared to historic outcomes without the use of cranial orthotics postoperatively.

The endoscopic procedure is a minimally invasive technique where bone segments are removed, releasing the fusion. Since no plates or screws are inserted, cranial orthotics can be used to maintain the surgical correction postoperatively. Postoperative cranial banding is frequently used to maintain reshaping following endoscopic surgery for craniosynostosis. Only a few published, uncontrolled case series studies have described the use of postoperative cranial orthoses as an adjunct to surgery (Cohen, 2004; Jimenez, 2007; Jimenez, 2010; Murad, 2005). These investigators propose that postoperative cranial orthoses are a valuable tool in enhancing the surgical outcome.

Non-Synostotic Plagiocephaly

In plagiocephaly without synostosis, also referred to as non-synostotic plagiocephaly, the sutures of the skull remain open. This type of plagiocephaly can also be referred to as positional or deformational plagiocephaly when it is due to environmental factors including, but not limited to, premature birth, restrictive intrauterine environment, birth trauma, torticollis, cervical anomalies, and sleeping position.

Plagiocephaly, regardless of suture closure status, can be classified as either brachycephaly or scaphocephaly. Brachycephaly refers to a head shape that is not asymmetric but is disproportionately short, with the head being abnormally wide. Scaphocephaly is the opposite, with the head being abnormally narrow.

The incidence of plagiocephaly and brachycephaly increased rapidly as a result of the “Back to Sleep” campaign initiated in 1992 by the American Academy of Pediatrics (AAP), in which a supine sleeping position is recommended to reduce the risk of sudden infant death syndrome (SIDS). It is estimated that 1 of every 60 neonates may have some degree of plagiocephaly or brachycephaly. Positional plagiocephaly typically consists of right or left occipital flattening with advancement of the ipsilateral ear and prominence of the ipsilateral frontal region, 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. Assessment of plagiocephaly and brachycephaly are based on anthropomorphic measures of the head, using anatomical and bony landmarks.

There are three basic options for treating non-synostotic plagiocephaly; no therapy, repositioning therapy, and the use of cranial orthoses. Repositioning therapy includes supervised “tummy time,” or placement of the child in a half supine position with a towel or blanket roll behind the shoulder to position the occiput away from the flat side. Physical therapy may also be recommended, particularly if there is shortening or tightening of the sternocleidomastoid muscle. Treatment with a cranial orthosis involves the use of an adjustable band or helmet that is custom-molded to the infant’s head and can progressively mold the shape of the cranium by applying corrective forces to the frontal and occipital prominences, leaving room for growth in the adjacent flattened areas. Treatment with cranial orthoses is typically initiated around 4 to 6 months of age, frequently after a prior trial of repositioning therapy, and continues for an average of 4 to 5 months. Both helmets and cranial bands are recommended to be worn 15-22 hours per day with treatment extending over 3 to 4 months. Daily time without the orthotic, usually at least 1 hour, is required for skin care and hygiene.

Teichgraeber and colleagues (2002) evaluated the effectiveness of cranial orthotic device therapy in the correction of infants with moderate to severe deformational plagiocephaly. The authors concluded that the use of a cranial orthotic device was effective for correcting cranial vault and cranial base asymmetries. In this study, a total of 248 infants were treated with the DOC band. Cranial asymmetry was evaluated using 18 anthropometric measurements; cranial vault asymmetry was defined as the distance between the left frontozygomatic point and the right euryon point minus the distance between the right frontozygomatic point and the left euryon point. Cranial base asymmetry used the inion point to the right tragus point minus the inion point to the left tragus point. Infants that presented with moderate to severe posterior deformation plagiocephaly received DOC band therapy and had anthropometric measurements at 8-week intervals. The mean cranial vault asymmetry improved from 8.53 mm to 4.98 mm ($p=0.0002$). The cranial base asymmetry improved from 7.08 mm to 4.23 mm ($p<0.0001$). The limitations of this study included its retrospective design and the lack of comparative data from a group treated with positioning alone.

A study by Graham and colleagues (2005) compared the effect of repositioning versus helmet therapy on the cephalic index in infants referred for brachycephaly. This nonrandomized controlled study collected longitudinal data on 193 infants referred and treated for abnormal head shapes at a single institution between 1997 and 2001. The cephalic index was compared before and after treatment with either repositioning or helmet therapy. In a subgroup of infants (n=92) with severe brachycephaly (cephalic index greater than or equal to 90%), the authors concluded that although both groups (repositioning and orthotic) improved, repositioning was less effective than cranial orthotic therapy based on reduction in cephalic index (2.5% vs. 5.3%). The limitations of this study include a lack of randomized design, baseline differences in initial mean age and cephalic index, and differences in mean duration of therapy between the two treatment groups.

Hutchison and colleagues (2011) conducted a prospective case series study of 161 participants with deformational plagio- or brachycephaly. At baseline, 47% of participants were in the severe range, 31% were in the moderate range and 22% were in the mild range. At follow-up, 77 (61%) of the participants had achieved the normal range for head shape, and only 5 (4%) were in the severe range. The authors report that they saw reductions in overall severity levels and that many participants with severe initial conditions were in the normal range at follow-up.

Seruya and colleagues (2013) conducted a prospective case series study of 346 participants with non-synostotic plagiocephaly undergoing cranial orthotic therapy. Their analysis involved stratification of participants into 7 different age groups, beginning with those under 20 weeks to those greater than 40 weeks. Duration of therapy was found to be positively correlated with age of treatment initiation ($r=0.089$, $p<0.05$). The authors report that normalization of head shape was fastest in the youngest cohort (Group 1 [less than 20 weeks], n=26). The rate of change in transcranial difference measurements was negatively correlated with age of treatment initiation ($r=-0.88$, $p<0.05$). As such, the later a participant had treatment initiated, the longer it took to achieve normalization. This is supported by the observation of a logarithmic decrease in rate of asymmetry improvement with increasing age. Furthermore, children in the two oldest groups, Group 6 (ages 36-40 weeks, n=29) and Group 7 (greater than 40 weeks, n=43), did not achieve full correction despite similar treatment duration and compliance to the other groups. In the discussion section, the authors postulated that, given the data presented, treatment with cranial orthotics could conceivably be used in toddlers. However, success is likely to be negatively impacted by the requirement of long treatment times and problems with compliance in older children. The durability of improvement was not reported.

A large, retrospective case series study was conducted by Couture and colleagues (2013) and involved 1050 participants. In addition to stratifying the results by participant age, stratification was also done according to the severity of plagiocephaly as measured by Argenta classification. The results indicated that the degree of head deformation significantly impacted treatment times, with Type III, IV, and V deformities having significantly longer times to correction (53%, 75%, 81% longer, respectively; $p<0.0001$). In contrast to the results reported by Seruya, no differences were reported with regard to the time to correction according to age group. In this study, participants in the oldest age group (greater than 12 months) did not have a statistically significant longer time to improvement when compared to the youngest age group (less than 3 months). As with the Seruya study, the authors reported that children up to 18 months of age can benefit from correction, although their findings indicate that these older participants would have similar treatment duration to younger children. The authors commented that they suspect that the older groups had such positive outcomes mostly due to highly motivated parents overseeing compliance. Finally, the devices used in this trial were off the shelf models, and it was pointed out that they demonstrated outcomes similar to those previously reported with custom made models. The authors state that this indicates that the use of more complicated custom orthotics is not needed to achieve positive outcomes.

Van Wijk and colleagues (2014) reported on the results of a single-blind randomized controlled trial (RCT) involving infants aged 5 to 6 months with moderate to severe skull deformation who were born after 36 weeks of gestation with no muscular torticollis, craniosynostosis, or dysmorphic features. Out of 403 possible participants, parents of 84 infants agreed to participate (20.8%). Participants were assigned to receive helmet therapy (n=42) or to a control group with the natural course of the condition (n=42). At baseline, the control group participants had significantly more plagiocephaly demonstrated by a higher oblique diameter difference index ([ODDI] mean 109.2 versus 107.2; $p<0.05$). The helmet group had significantly more participants with brachycephaly, the cranioproportional index (CPI) mean was 93.4 compared to 90.3 in the control group ($p<0.05$). At 24 months, 79 (94%) participants were available for final assessment. Only 10 of the helmet group participants used the helmet until 12 months of age, as specified by the protocol. Of the remaining 20 helmet group participants, 8 ceased treatment early due to satisfaction with treatment outcomes, 10 stopped due to side effects, and 1 was not satisfied with the results. Details from the last participant were not available. Fitting problems with the helmet were described in 22 of the 30 (73%) helmet participants that completed the 24-month follow-up. Between groups, no differences were noted for ODDI change scores as the helmet group mean was 2.9 compared with 3.1 from the control group ($p=0.8$), CPI change score mean for the helmet group was 7.0 versus control group mean 6.8 ($p=0.81$). No significant differences were found in outcomes when the intent to treat analysis was compared to the per protocol analysis. The authors reported

no differences between groups with regard to motor development, sleep quality, or duration of crying. All helmet group parents reported some side effects, including skin irritation, augmented sweating, helmet odor, and helmet associated pain. The authors acknowledge several limitations in this study, including a significant difference between groups with regard to the severity of skull deformation, a low participation rate ("not powered for equivalence"), difference in education level between parents participating in the study and those who refused, and no true assessment of daily helmet wear times. Despite the acknowledged study shortcomings, the authors conclude that helmet therapy is not superior to natural course of therapy.

Freudlsperger and colleagues (2016) conducted a study of 213 infants treated with helmets between 2011 and 2014. The infants were divided into 3 groups by age when therapy was initiated. Group 1 were infants ages 24 weeks or less (n=82), group 2 were infants ages 24-32 weeks (n=75), and group 3 were infants greater than 32 weeks of age (n=56). The groups were then categorized by severity of the Cranial Vault Asymmetry Index (CVAI). The categorization of mild (CVAI 3-7 %), moderate (CVAI 7-12%), and severe (CVAI greater than 12%) were assigned. The duration of treatment on average was 18.1 weeks for Group 1, 18.9 weeks for Group 2, and 19.8 weeks for Group 3. The study indicated Group 1 produced the highest correction rate of 56% and the largest reduction of the initial CVAI was noted in same group of infants with severe plagiocephaly. Group 2 demonstrated an improvement of 59% while Group 3 showed an improvement of 31%. A high statistical significance was observed when the infants were grouped by severity of CVAI (p=0.0001). The authors concluded that starting an early therapy for infants with moderate to severe signs of plagiocephaly is recommended to allow sufficient time for effective helmet therapy.

Han and colleagues (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. Participants 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.

Mackel and colleagues (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 participants 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 participants who began therapy after 6 months (7.4 ± 2.9 vs. 9.4 ± 2.1%, p=0.01; 4.5 ± 2.8 vs. 6.4 ± 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.

Kunz and colleagues (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.

Picart and colleagues (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 ± 6%, and with therapy improved to 96.7 ± 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.

Other Considerations

The American Academy of Pediatrics (AAP) states that there is no evidence that molding helmets work any better than repositioning therapy for infants with mild to moderate skull deformity (Laughlin, 2011). They recommend repositioning as the initial treatment for infants younger than 6 months. For infants with severe deformity, the AAP states that the use of skull-molding helmets is most effective between the ages of 4-12 months and beyond the age of 12 months cranial remodeling is less, and compliance issues increase.

In a 2016 guideline for the treatment of pediatric positional plagiocephaly, the Congress of Neurological Surgeons (CNS) states:

> When judging the totality of the evidence, it appears that currently accepted management of positional plagiocephaly in infants—using conservative therapy (repositioning and physical therapy) for the treatment of mild/moderate deformity in younger infants and reserving helmet therapy for more severe deformity, especially in those older infants who have failed to see improvement with conservative measures—can be justified by the data.

It should be noted that the use of cranial orthoses is not risk-free. Wilbrand and colleagues (2012) conducted a retrospective case series study involving 410 participants with moderate to severe non-synostotic plagiocephaly. The authors reported a significant number of complications in this population, including pressure sores (10.5%), ethanol erythema (6.3%), skin infections (1.2%), and bacterial abscess (0.2%). They also reported a 1.5% treatment failure rate. The use of cranial banding is also contraindicated for individuals with hydrocephalus.

Under normal circumstances, a baby'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 orthosis. Under such circumstances, it is reasonable to provide the child with a new orthosis when continued significant improvement in cranial shape is anticipated.

In compliance with federal Early and Periodic Screening, Diagnosis and Treatment (EPSDT) requirements to provide “other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services,” it is acknowledged that cranial orthosis may be considered medically necessary when provided for children with the most severe skull deformities, particularly when coexistent with medical conditions associated with limited mobility. The application of the cranial orthosis does not replace the need for appropriate counter positioning education for caregivers and provision of skilled physical therapy when indicated.

Definitions

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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 counter clockwise 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).

Brachycephaly: 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.”

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: A condition characterized by an abnormal head shape, usually flattening on one side of the back of the head, and 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 plagiocephaly.”

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.

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O & P Cranial Molding Helmet™

P.A.P. Orthosis™

Plagiocephalic Applied Pressure Orthosis™

RHS Cranial Helmet™

STARband™ Cranial Remolding Orthosis™

STARlight™ Cranial Remolding Orthosis™

Static Cranioplasty Orthosis™

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information, References and Websites for Additional Information sections.
	09/27/2023	Updated Coding section with 10/01/2023 ICD-10-CM changes; added Q75.001-Q75.08 replacing Q75.0.
Reviewed	02/16/2023	MPTAC review. Updated References and Websites for Additional Information sections.
Reviewed	02/17/2022	MPTAC review. Updated Discussion, References and Websites for Additional Information sections.
Revised	02/11/2021	MPTAC review. Updated formatting in the “Clinical Indications” section. Removed condition results from indication, added three additional anthropometric measurement indications to Reconstructive Position Statement and removed one anthropometric measurement indication. Discussion/General Information, Definitions, References, and Websites sections updated.
Reviewed	11/05/2020	MPTAC review. Discussion/General Information, References, and Websites sections updated. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Discussion/General Information, References, and Websites sections updated.
Reviewed	01/24/2019	MPTAC review. Updated formatting in Clinical Indications section. Coding, Discussion/General Information, References, and Websites sections updated.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Discussion/General Information, References and Website sections.
Revised	02/02/2017	MPTAC review. Added “Reconstructive” section and included criteria for non-synostotic skull deformity. In the “Reconstructive” section, the criterion for documentation of gross motor development expressed as developmental quotient during the interval since the initial application was removed and added language of at least two months of home management with repositioning either before or after the initial application for infants without cervical motion restriction. In the “Medically Necessary” section, added language for the use of an adjustable cranial orthosis is considered medically necessary in the post-operative management of infants following endoscopic repair of craniosynostosis. Updated formatting in the “Clinical Indications” section. Updated Discussion and References section.
Reviewed	02/04/2016	MPTAC review. Removed ICD-9 codes from Coding section.
Revised	02/05/2015	MPTAC review. Added medically necessary language for new orthosis when inadequate therapeutic positioning occurs due to head growth and continued benefit is anticipated. Updated Discussion, References, and Definitions sections.
Reviewed	02/13/2014	MPTAC review. Updated Discussion and Reference sections.
New	02/14/2013	MPTAC review. Initial document development.