**Cranial Remodeling Bands and Helmets AHM**

**Clinical Indications**

- **Cranial remodeling bands** (or helmets) are considered medically necessary orthoses for treatment of moderate to severe positional head deformities associated with premature birth, restrictive intrauterine positioning, cervical abnormalities, birth trauma, torticollis (shortening of the sternocleidomastoid muscle) and sleeping positions in children when banding is initiated at 3 to 12 months of age and **ALL** of the following conditions are met
  - A 2-month trial of conservative therapy consisting of repositioning the child's head such that the child lies opposite to the preferred position, has failed to improve the deformity and is judged to be unlikely to do so
  - **1 or more** of the following must be met
    - Anthropometric data (measurements used to evaluate abnormal head shape by measuring the distance in mm from one pre-designated point on the face or skull to another, comparing the right and left sides) verifies that a moderate to severe plagiocephaly is documented by a physician experienced in such measurement. **[A]** A difference of asymmetry greater than 6 mm between anthropometric measurements in any of the anthropometric data in the following table warrants coverage of a trial of orthotic banding to correct the craniofacial deformity including **1 or more** of the following
      - Cranial Base from right to left subnasal point to tragus measures maxillary depth or right left morphological face height
      - Cranial vault from frontozygomaticus point (fz) on one side of face to euryon (eu) measures cranial vault asymmetry
      - Orbitotragial depth(ex-t, R, L) from exocanthion point (ex) to tragus (t) measures orbitotragion depth (exocanthion)
    - For brachycephaly evaluation, **[B]** a cephalic index 2 standard deviations below mean (head narrow for its length) or 2 standard deviations above mean (head wide for its length) warrants coverage of a trial of orthotic banding to correct the craniofacial deformity in a child after 4 months of age and before 12 months of age including **ALL** of the following
      - Head width from euryon (eu) on one side of head to euryon (eu) on the other side measures greatest transverse diameter or maximal head width
      - Head length from glabella point (g) to opisthocranion (op) measures maximal head depth or length
    - Cephalic index = Head width (eu - eu) x 100 /Head length (g - op)
Infants who develop significant plagiocephaly secondary to a constant head position required for long-term hyper-alimentation who do not respond to simple changing of the catheter location allowing the head to be repositioned

- Patients with excess frontal bossing secondary to sagittal synostosis
- Patients with moderate to severe residual plagiocephaly after surgical correction
- Premature infants with dolichocephalic head shape who have developed a mis-shapen head secondary to sustained head position

A second cranial remodeling band or helmet is considered medically necessary for children who meet the afore-mentioned criteria if the asymmetry has not resolved after 2 to 4 months such that the severity of head deformity indicates another orthosis and the orthosis becomes ill-fitting after attempts to adjust and leaves little or no room for new growth. A second orthosis may be medically necessary to prevent regression of head shape in very young infants (8 months or younger) who met the aforementioned criteria at the initiation of therapy, who have outgrown the initial orthosis, and have not developed midline head control, rolling, or sitting.\[^C\]

Cranial remodeling band (or helmet) is considered medically necessary for infants with synostotic plagiocephaly to correct continued asymmetry following surgery (i.e., a trial of conservative therapy is not needed when the cranial remodeling band is used following surgery for synostotic plagiocephaly).

- The use of a cranial remodeling band (or helmet) without surgery to correct asymmetry in infants with synostotic plagiocephaly is considered investigational. Craniosynostosis that is not surgically corrected is a contraindication to use of cranial remodeling bands or helmets.

- The use of a cranial remodeling band (or helmet) is considered cosmetic for persons not meeting the above criteria.

Current role remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See Inappropriate Uses for more detailed analysis of the evidence base. The use of sleep positioning wrap for the treatment of infants with positional head shape deformities is considered investigational because its effectiveness has not been established.

Current role remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See Inappropriate Uses for more detailed analysis of the evidence base. Cranial remodeling helmets and bands are contraindicated and not medically necessary in unshunted or uncontrolled hydrocephalus.

**Evidence Summary**

- **Background**
  - Plagiocephaly (an asymmetrical head shape) is most often the result of an infant spending extended period of time on their back, typically during sleep. Plagiocephaly can also occur as a feature of other disorders (e.g., craniofacial disorders, torticollis, cervical anomalies) and is categorized as either positional or synostotic (premature union of cranial sutures). Although 1 in 300 infants’ exhibit variable degrees of plagiocephaly, true
sutural synostosis, which interferes with cranium development and may cause increased intracranial pressure, occurs in only 0.4 to 1 per 1000 live births.

- Positional plagiocephaly is treated conservatively and many cases do not require any treatment as the condition may resolve spontaneously when the infant begins to sit up. When the deformity is moderate or severe and a trial of repositioning the infant has failed, a pediatric neurologist, neurosurgeon or other appropriate specialist in craniofacial deformities may prescribe a cranial remodeling band to remodel the misshapen head. The custom molded orthotic is designed to fit a child’s head for two to four months.

- Examples of brands of cranial remodeling bands and helmets include the DOC BAND®, Gillette Children's Craniocap, and the STARband™ Cranial Headband. Average treatment time with the cranial remodeling band or helmet is 4.5 months.

- A systematic evidence review of cranial orthosis treatment for infant deformational plagiocephaly prepared for the UK National Health Services (NHS QIS, 2007) found no randomized controlled trials assessing the effectiveness of cranial orthoses for the treatment of deformational plagiocephaly were identified. The assessment stated that no evidence-based conclusions can be reached on the effectiveness of cranial orthoses due to the limited methodological quality of the available trials. "Further research in the form of a randomised controlled trial is needed to determine the true effectiveness of cranial orthoses."

- While infants with positional plagiocephaly may be treated with head positioning and/or helmeting, the standard treatment for synostotic plagiocephaly (asymmetrical head caused by premature closure of the cranial sutures) is surgery. There is some evidence suggesting that a cranial remodeling band (or helmet) may improve outcomes following surgery to treat synostotic plagiocephaly. Seymour-Dempsey et al (2002) retrospectively reviewed the results of surgery alone (n = 6) versus surgery and postoperative banding (n = 15) in treating children diagnosed with sagittal synostosis. The investigators reported that correction toward a normal cephalic index was seen in the banded group throughout the course of treatment, while this trend was not present in the non-banded group.

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

- In a randomized controlled trial, Hutchison et al (2010) examined the effectiveness of the Safe T Sleep positioning wrap in infants with positional head shape deformities. A total of 126 infants presenting to a plagiocephaly clinic were randomized to either positioning strategies or to positioning plus the use of a Safe T Sleep positioning wrap. Head shape was measured using a digital photographic technique, and neck function was assessed. They were followed-up at home 3, 6 and 12 months later.

- There was no difference in head shape outcomes for the 2 treatment groups after 12 months of follow-up, with 42 % of infants having head shapes in the normal range by that time; 80 % of children showed good improvement. Those that had poor improvement were more likely to have both plagiocephaly and brachycephaly and to have presented later to clinic. The authors concluded that most infants improved over the 12-month study period, although the use of a sleep positioning wrap did not increase the rate of improvement.
• Larsen (2004) stated that a second orthosis is rarely required but could be used in very severe head deformations, unusual circumstances (illness-negated use or if the child has serious health and/or positioning issues), or unusually high expectations of the family. The author noted that criteria for determining a second orthosis include the following:
  o Despite every effort, the orthosis becomes ill-fitting or leaves little or no room for new growth
  o If age and severity indicate another orthosis and parents are willing to continue
  o If prescribed for use as a continued post-operative adjunct or for preventative measures
• The American Academy of Orthotists and Prosthetists' draft consensus statement on "Orthotic management of deformational plagiocephaly (AAOP, 2004) stated that "very young infants who have not developed midline head control, rolling, or sitting, may require a second orthosis to prevent regression of the head shape". The AAOP stated that a second orthosis is rarely required but may be used in cases of increased severity, extenuating circumstance (infant with multiple health issues), or a very young infant (less than 3 months). Criteria for use of a second orthosis include ill-fitting orthosis after multiple attempts to adjust, age/severity indicators with a willingness to continue by the family, post-operative adjunct/ preventative measures.
• The guideline also noted that termination of the orthotic treatment program is recommended, without weaning, when head shape falls within normal limits. If unresolved torticollis exists or if sleeping patterns are poor (same side as flatness), use is continued for an additional 2 to 4 weeks. Furthermore, unshunted or uncontrolled hydrocephalus as well as craniosynostosis are contraindications for cranial remolding orthosis
• Chan and colleagues (2013) noted that craniosynostosis results in characteristic skull deformations. Correction of craniosynostosis has traditionally involved an open cranial vault remodeling (CVR) procedure. A technique recently developed endoscope-assisted craniectomy (EAC) repair in conjunction with a post-operative molding helmet to guide cranial growth. Few studies compared these 2 approaches to the treatment of the various forms of craniosynostosis. These investigators presented a single institution's experience with open CVR and EAC. This study was a retrospective review of 57 patients who underwent craniosynostosis repair by either the endoscope-assisted or open techniques; and compared operating room times, blood loss, volume of transfused blood, length of hospital stay, and overall costs.
  The endoscopic technique was performed on younger children (4.7 months versus 10.6 months, p = 0.001), has shorter operating room times (2 hours 13 minutes versus 5 hours 42 minutes, p = 0.001), lower estimated blood loss (74.4 ml versus 280.2 ml, p = 0.001), less transfused blood (90.6 ml versus 226.9 ml), shorter hospital stays (1.2 days versus 4.9 days, p = 0.001), and decreased cost ($24,404 versus $42,744, p = 0.008) relative to the traditional open approach. The authors concluded that issues with the endoscope-assisted procedure primarily concerned the post-operative helmet regimen, specifically patient compliance (17.1 % non-compliance rate) and minor skin breakdown (5.7 %). The endoscope-assisted repair with post-operative helmet molding therapy was a cost-effective procedure with less operative risk and minimal post-operative morbidity. This was a valuable treatment option in younger patients with compliant care-givers.
• Vogel and associates (2014) stated that the surgical management of infants with sagittal synostosis has traditionally relied on open CVR techniques; however, minimally invasive technologies, including EAC repair followed by helmet therapy (HT, EAC+HT), is increasingly used to treat various forms of craniosynostosis.
during the 1st year of life. These researchers determined the costs associated with EAC+HT in comparison with those for CVR. They performed a retrospective case-control analysis of 21 children who had undergone CVR and 21 who had undergone EAC+HT. Eligibility criteria included an age less than 1 year and at least 1 year of clinical follow-up data. Financial and clinical records were reviewed for data related to length of hospital stay and transfusion rates as well as costs associated with physician, hospital, and outpatient clinic visits.

- The average age of patients who underwent CVR was 6.8 months compared with 3.1 months for those who underwent EAC+HT. Patients who underwent EAC+HT most often required the use of 2 helmets (76.5 %), infrequently required a 3rd helmet (13.3 %), and averaged 1.8 clinic visits in the first 90 days after surgery. Endoscope-assisted craniectomy plus HT was associated with shorter hospital stays (mean of 1.10 versus 4.67 days for CVR, p < 0.0001), a decreased rate of blood transfusions (9.5 % versus 100 % for CVR, p < 0.0001), and a decreased operative time (81.1 versus 165.8 minutes for CVR, p < 0.0001).

- The overall cost of EAC+HT, accounting for hospital charges, professional and helmet fees, and clinic visits, was also lower than that of CVR ($37,255.99 versus $56,990.46, respectively, p < 0.0001). The authors concluded that EAC+HT were a less costly surgical option for patients than CVR. Furthermore, EAC+HT were associated with a lower utilization of peri-operative resources. The authors stated that these findings suggested that EAC+HT for infants with sagittal synostosis may be a cost-effective 1st-line surgical option.

- Hinchcliff et al (2013) stated that the current treatment of craniosynostosis is open surgical excision of the prematurely fused suture and CVR. Due to the change in skull morphology and the increase in volume, some tension on the skin flaps is noted with closure. Although complete wound breakdown is rare, it can be a devastating complication. These researchers presented their experience with the use of the SPY imaging system (Lifecell Corporation, Branchburg, NJ) to visualize and record blood flow within the flaps of a 1-year old patient with anterior plagiocephaly. The authors concluded that intra-operative indocyanine green angiography has the potential to be a significant advantage in such cases, providing a safe and objective method to assess intra-operative scalp perfusion, allowing the surgeon to take additional measures to ameliorate any ischemic problems.

References


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Footnotes

[A] These measurements are generally obtained by the orthotist fitting the band or helmet. The most significant measurements used in this initial evaluation are skull base asymmetry, cranial vault asymmetry, orbitotragal depth, and cephalic index. [ A in Context Link 1 ]

[B] These measurements are generally obtained by the orthotist fitting the band or helmet [ B in Context Link 1 ]

[C] remodeling bands (or helmets) are contraindicated and considered not medically necessary after 2 years of age [ C in Context Link 1 ]

Codes

CPT® or HCPCS: 97762, L0112, L0113, S1040