Clinical Policy Title: Cranial orthotic devices for positional plagiocephaly

Clinical Policy Number: 11.02.01

Effective Date: September 1, 2013
Initial Review Date: February 18, 2013
Most Recent Review Date: August 19, 2015
Next Review Date: August 2016

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of cranial orthotic devices to be clinically proven and, therefore, medically necessary when the following criteria are met:

- For infants where treatment is initiated between three and twelve months of age, and where there has been failure of a three-month trial of conservative therapy such as repositioning and physical therapy.
- A cranial orthotic may be required for children under age 18 months in the post-operative period after authorized surgery on cranial structures.

Limitations:

Policy contains:
- Positional or deformational cranial asymmetries in infants.
- Repositioning and physical therapies.
- Prevention.
Cranial orthotics should not be used in children under the age of 3 months or those who have not had physical or repositioning therapy over a two-month period. Only cranial orthotics custom-made for the individual child will be covered. Use of cranial orthotics for treatment of uncorrected craniosynostoses is not approved by the FDA and is considered investigational and not medically necessary. All other uses of cranial orthotics are not medically necessary.

**Alternative covered services:**

Physician office visits and physical therapy services within covered benefits.

**Background**

Positional skull deformities are common, with an estimated incidence range from 1 in 300 live births to as high as 48 in 100 children at age 12 months. This wide variation reflects variation in the definitional sensitivity of positional skull deformities, or positional plagiocephaly. The condition is thought to arise from asymmetrical pressures on the bony plates of the immature skull. Such pressures may arise in utero (e.g., from breech presentation) or in the first 12 to 18 months of life. A significant increase in the incidence of positional plagiocephaly began in 1992 after the American Academy of Pediatrics and the National Institute of Child Health and Human Development initiated the “Back to Sleep Campaign,” now known as the “Safe to Sleep” program. This program has resulted in a 50 percent reduction in sudden infant death syndrome (SIDS), but has had a six-fold increase in benign positional plagiocephaly. Infants with this condition are generally treated with repositioning therapy and/or physical therapy. Other causes of positional plagiocephaly include torticollis or “wry neck,” also associated with prematurity.

Positional plagiocephaly is generally considered a benign condition which does not threaten life, health, development or intellectual capability. Studies show that cranial asymmetry will resolve spontaneously with no intervention in 42 percent of cases. The use of physical therapy and/or repositioning techniques have further improved final cranial symmetry. Use of cranial orthotics, either a band or a helmet, has been recommended by the American Academy of Pediatrics for infants with mild to moderate cranial asymmetry who have had a significant trial of physical therapy and repositioning management for two to three months and have failed to improve. Cranial orthotics are typically used between the ages of 4 and 12 months but may be used up to age 18 months. Aside from cost barriers, there have not been any significant medical complications identified with the use of cranial orthotics.

The significant diagnosis of craniosynostosis should be differentiated from positional plagiocephaly. Craniosynostosis occurs from lambdoidal or coronal unilateral fusion. This is much rarer than seen spontaneously, and usually found in 6 or 7 cases per 100,000 live births. Molding helmets or orthotics are used only in the post-operative period for children who have had surgery to correct craniosynostosis. Generally, cranial orthotics are not used for children with fusion of the sutures of the skull.
American Academy of Orthotists and Prosthetists guidelines (2011) make the following recommendations:

- Cranial molding orthoses should be considered in the management of deformational plagiocephaly.
- Repositioning techniques and therapy are viable treatments for infants with deformational plagiocephaly.
- Allied health professionals should be aware of their role in the identification and prevention of deformational plagiocephaly.
- Allied health care providers should be educated on the indications for referring infants for a cranial molding orthotic.
- Scientific literature on the natural course of untreated deformational plagiocephaly is lacking.
- Parents should learn about the potential for head shape deformities in prenatal and postnatal information provided at the hospital.

Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on June 25, 2014, using the terms “positional plagiocephaly,” “cranial orthotic devices,” and “helmet therapy.” We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
**Findings**

- While the methodologic quality of the literature is generally poor, systematic reviews and guidelines concur that orthotic devices provide better correction of deformational skull asymmetries than repositioning or physical therapy alone.
- Positional plagiocephaly is not associated with intellectual or developmental disabilities and may be prevented by education of infant caregivers.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content</th>
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<tbody>
<tr>
<td>Cincinnati Children's Hospital (2012) Caregiver education to prevent positional plagiocephaly</td>
<td><strong>Key points:</strong> Caregivers of infants should routinely receive information regarding “tummy time” and infant positioning beginning prior to age 2 months to decrease the time infants spend in positions other than supine and decrease the incidence of plagiocephaly.</td>
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</tbody>
</table>
| Cincinnati Children's Hospital (2011) Prognosis of infant development with plagiocephaly, torticollis | **Key points:**  
- Parents wishing to know if their child’s development will be affected by head shape should know that shape is not a predictor of developmental delay.  
- Developmental delay in very young infants (< 22 weeks) appears related to sleep position, muscle tone, activity level, male gender and neck dysfunction. |
| Hayes (2010) Cranial orthotic devices | **Key points:** Moderate level of evidence for reduction or elimination of asymmetry when therapy initiated before 12 to 18 months:  
- Hayes rating B: Infants with positional plagiocephaly who have not responded adequately to reposition and/or physical therapy or who are unlikely to respond due to age or severity of deformity, when therapy is initiated before 12 – 18 months and considered necessary to avoid surgery or complications due to future mandibular or auricular asymmetry.  
- Hayes D: Lack of evidence for patients with head deformities due to uncorrected cranial synostosis or hydrocephalus and for preventing or correcting neurodevelopmental delay or disability. |
| Xia (2008) Nonsurgical treatment of deformational plagiocephaly | **Key points:**  
- Seven cohort studies (N = 881); 10 – 176.  
- Mix/inconsistent prospective and retrospective.  
- “Considerable” evidence molding therapy may be more effective at reducing skull asymmetry than repositioning, but studies may be biased. |
| NHS Quality Improvement Scotland (2007) Cranial orthoses for infant deformational plagiocephaly | **Key points:**  
- No randomized controlled trials (RCTs); no conclusions possible and research needed. |
### Key points:

- Conclusions re relative effectiveness of interventions not feasible due to poor methodology but counter positioning with/without helmets or physical therapy appeared to consistently reduce skull deformity.

### Key points:

- Condition largely preventable by alternating head positions during sleep, minimizing prolonged periods in supine position and using prone positions while awake in infants < 6 months.
- Orthoses should be used only for moderate/severe asymmetries and after six- to eight-week trial of repositioning.
- Orthoses are safe when prescribed by experienced qualified providers and used as directed.
- Cases series and non-randomized CCTs: effective in reducing cranial asymmetries.
- RCTs are needed.

### Glossary

**Cephalic index** — The ratio of the cranial width to the cranial length.

**Cranial orthotic** — An orthotic device designed to use pressure to realign the plates of the skull to create a symmetrical and rounded skull.

**Craniosynostosis** — Premature closure of one or more of the sutures of the skull.

**Hydrocephalus** ("water on the brain") — An abnormal accumulation of cerebrospinal fluid within brain cavities. It may result in increased intracranial pressure and associated neurologic problems such as convulsion, tunnel vision or mental disability and can be life-threatening.

**Orthotics** — A device, brace or splint used to provide support and alignment.

**Plagiocephaly** — An asymmetrical deformity of the skull due to premature closure of the lambdoidal and coronal sutures on one side, which results in an oblique slant.

**Synostosis** — The premature fusion of one or more cranial sutures, often resulting in an abnormal head shape. It may result from a primary defect of ossification (primary cranial synostosis) or from failure of brain growth (secondary craniosynostosis).

- **Simple craniosynostosis** — A single prematurely fused suture.

- **Complex or compound craniosynostosis** — Involvement of multiple sutures.
- Syndromic craniosynostosis — When children with complex craniosynostosis also exhibit other physical deformities.

Torticollis (“wry neck”) — A dystonic condition characterized by abnormal asymmetric head or neck positions due to a variety of causes, congenital or acquired, including birth trauma, intrauterine malposition, scarring or disease of cervical vertebrae, inflammation, and infant positioning.

References

Professional society guidelines/other:

Cincinnati Children’s Hospital Medical Center. Best evidence statement (BESt). Use of caregiver education to prevent positional plagiocephaly. Cincinnati, OH: Cincinnati Children’s Hospital Medical Center; 2012.

Cincinnati Children’s Hospital Medical Center. Best evidence statement (BESt). Prognosis of infant development with plagiocephaly, torticollis. Cincinnati, OH: Cincinnati Children’s Hospital Medical Center; 2011.


Peer-reviewed references:


**Clinical trials:**


**CMS National Coverage Determinations (NCDs):**

No NCDs found as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs found as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<tr>
<td>A8002</td>
<td>Helmet, protective, soft, custom fabricated, includes all components and accessories</td>
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<tr>
<td>A8003</td>
<td>Helmet, protective, hard, custom fabricated, includes all components and accessories</td>
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<td>S1040</td>
<td>Cranial remolding orthotic, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)</td>
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<td>756.0</td>
<td>Congenital anomalies of skull and face bones</td>
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<td>V45.8</td>
<td>Other post-procedural status</td>
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<td>Z98.89</td>
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