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 17, 2016
Next Review Date: August 2017

Related policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’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 Keystone First 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. Keystone First’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. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First 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 12 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.
- Cranial orthotics which are custom-made for the individual child.

Limitations:

Cranial orthotics should not be used in children under the age of three months or those who have not had physical or repositioning therapy over a two-month period. Use of cranial orthotics for treatment of uncorrected craniosynostosis 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:

- Positional plagiocephaly (PP).
- Cranial orthotic devices.
- Craniosynostosis.
Physician office visits and physical therapy services within covered benefits.

**Background**

Positional skull deformities are common, with an estimated incidence range from one 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 (PP). 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 PP 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 PP. Infants with this condition are generally treated with repositioning therapy and/or physical therapy. Other causes of PP include torticollis or “wry neck,” also associated with prematurity.

PP is generally considered a benign condition that 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. One study found that the PP incidence declined with age after early infancy (16.0 percent at six weeks, 19.7 percent at four months, 6.8 percent at 12 months, and 3.3 percent at 24 months (Cummings 2011). However, another study shows that 39.7 percent of 63 children with the disorder required special education, namely speech, physical, and/or occupational therapy (Miller 2000).

The use of physical therapy and/or repositioning techniques have further improved final cranial symmetry. Use of cranial orthotics, either a band or 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 four 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. One study documented that of 380 healthy neonates, 23 were diagnosed with plagiocephaly at birth, but only nine of them still had the condition at age seven weeks (van Vimmeren 2007).

The significant diagnosis of craniosynostosis should be differentiated from PP. Craniosynostosis occurs from lambdoidal or coronal unilateral fusion. This is much rarer than seen spontaneously, and usually found in six or seven 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 (2004) 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**

Keystone First 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 July 15, 2016, 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, reviews and guidelines concur that orthotic devices provide better correction of deformational skull asymmetries than repositioning or physical therapy alone. Some treatments are relatively simple. The Canadian Paediatrics Society concluded that “tummy time” of 10 – 15 minutes per day, three times a day, was helpful in resolving any asymmetry from birth or infancy (Cummings 2011).

Numerous studies show that cranial orthotic devices are generally effective, including a systematic review of 42 studies (Goh 2013). A comparison of molding helmet therapy for positional brachycephaly with PP found that, while infants in both groups had significant diagonal difference (DD) reductions, those only in the PP group had normal head shapes after therapy (Teichgraeber 2004). A report on 298 infants with head asymmetry had a greater DD reduction when orthotics was used versus positioning (Graham 2005). Another report found that 171 Australian infants had a greater DD reduction after treatment with helmets, compared to those with no treatment (Ho 2016). In a group of infants with PP and undergoing helmet therapy, the average asymmetry index plunged from 9.8 percent to 5.4 percent (Freudlsperger 2016).

Other reports fail to conclude that cranial orthotic devices are more effective than other treatment choices (Hayes 2014). Several found greater improvement for helmets than for repositioning (Naidoo 2015 and Steinberg 2015). Mild complications are common, including adjusting helmets, removal by older children, intolerance by older children, and overheating in hot climates that cause rashes (Freudlsperger 2015). Another found that infants showed similar outcomes to those treated with helmets (Van Wijk 2014).

In a large-scale study of 1,011 Japanese infants with molding helmet therapy, symmetry of the head improved for both severe and mild cases, and benefits were greatest when therapy was started before the age of six months (Aihara 2014).

Treatment effectiveness may vary by the age of the infant. In a group of 213 patients with PP, the largest decline occurred in those beginning treatment with helmet therapy while under 24 weeks of age, compared to the 24 – 32 week and > 32 week groups (Freudlsperger 2016).

Quality of life increases have been documented; 46 Dutch children with PP and undergoing molding therapy had a quality of life rating rise from 3.6 to 7.5 after treatment, along with a 96 percent satisfaction rate (Grovaert 2008).

**Policy updates:**

Nineteen peer-reviewed references, eight of which were new since the 2015 writing of this policy, were added. Of these, five were included in the “summary of clinical evidence” section.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
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<tbody>
<tr>
<td>Ho (2016)</td>
<td>Efficacy of helmet therapy vs. no therapy in infants with cranial asymmetry</td>
</tr>
<tr>
<td>Key points:</td>
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<tr>
<td>171 Australian infants recruited in outpatient clinics with PP.</td>
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<td>Those with helmets had greater reduction in DD.</td>
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<tr>
<td>Source</td>
<td>Key points</td>
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<tr>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Aihara (2014)</td>
<td><strong>Key points:</strong></td>
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</table>
|                               | - 1,011 infants with molding therapy.  
|                               | - Head symmetry improved for both severe and mild cases.  
|                               | - Treatment especially helpful if started before age six months.                                                                                                                                                                                                               |
| Goh (2013)                     | **Key points:**                                                                                                                                                                                                                                                                                                                           |
|                               | - Systematic review, 42 studies, cranial orthoses effective in treating deformational plagiocephaly.  
|                               | - Noted that statistical significance may not square with clinical significance.  
|                               | - Consensus is treatment with helmet therapy does improve asymmetry and head circumference.  
|                               | - Although earlier treatment at no more than six months of age is preferred, children older than 12 months of age may still benefit.                                                                                                                                                                                                 |
| Cincinnati Children’s Hospital (2012) | **Key points:**                                                                                                                                                                                                                                                                                                                           |
|                               | - Caregivers of infants should routinely receive information regarding “tummy time” and infant positioning beginning prior to age two months to decrease the time infants spend in positions other than supine and decrease the incidence of PP.                                                                                                                                                     |
| Cincinnati Children’s Hospital (2011) | **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)                   | **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 PP 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)                     | **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.                                                                                                                                                                                                  |

**Glossary**

**Cranial orthotic device** — A custom-made device used to redirect growth of the skull bones to reduce cranial asymmetry.
Craniosynostosis — Premature closure of one or more of the sutures of the skull, causing problems with normal brain or skull growth, marked by asymmetry.

Molding helmet — A custom-designed device with a hard outer shell that applies gentle, persistent pressure in prominent areas of the head, allowing for growth in flattened areas.

Positional plagiocephaly (PP) — An asymmetrical deformity of the skull due to premature closure of the lambdoidal and coronal sutures on one side, which results in a flattening of the back or one side of the head, usually from lying in one position for long periods of time.

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:**

Searched clinicaltrials.gov on July 18, 2016 using terms “positional plagiocephaly” “cranial orthotic devices” and “helmet therapy.” Open Studies. Five studies found, none relevant.

**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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<td>Q75.9</td>
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<tr>
<td>Z98.89</td>
<td>Other specified post procedural states</td>
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<tbody>
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<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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<tr>
<td>S1040</td>
<td>Cranial remodeling orthotic, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)</td>
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