I. POLICY

It is the policy of MedStar Health, Inc. to cover cranial remolding orthoses when it is medically necessary and covered by the member’s specific benefit plan.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

II. DEFINITIONS

Cephalic Index (CI) – A cranial measurement used in the diagnosis of skull deformities. The cephalic index is calculated by dividing the width by the length and multiplying 100.

Congenital Muscular Torticollis (CMT) – is identified by a constriction of one side of the sternocleidomastoid muscle that flexes the head, turns it, and laterally rotates the head to one side. CMT is often associated with positional plagiocephaly.

Cranial remolding orthosis (CRO) – (also known as cranial modeling orthosis) (helmet or band) is a custom fitted device that is used in the treatment of positional (non-synostotic) plagiocephaly as a means to apply pressure to an infant’s cranium to improve its shape or symmetry.
Cranial base asymmetry (CBA) – the difference between the left and right sides of the cranial base (left cranial base minus right cranial base). This measurement determines ear asymmetry.

Cranial vault asymmetry (CVA) – the transcranial difference between the left and right sides of the cranial vault which is used in quantifying the deformity (left cranial vault minus right cranial vault).

Craniosynostosis – is a congenital deformity of the infant skull that occurs when the fibrous joints between the bones of the skull (called cranial sutures) close prematurely. Due to this closure, the baby develops an abnormally shaped skull because the bones do not expand normally with the growth of the brain.

Orbitotragial depth asymmetry (OTDA) – is the difference between the left and right sides of the superior facial bones which are used in quantifying the asymmetry (left orbitotragial depth minus right orbitotragial depth).

Positional brachycephaly – refers to a head shape that is short and wide. Infants with head shape often have a prominent or bossed forehead and increased cranial vault.

Positional plagiocephaly (also known as non-synostotic plagiocephaly) – is a condition in which specific areas of an infant’s head develop an abnormally flattened shape and appearance.

Positional scaphocephaly – refers to a head shape that is long and narrow.

III. PURPOSE

The purpose of this policy is to define criteria for Cranial Remolding Orthosis.

IV. SCOPE

This policy applies to various MedStar Health, Inc. departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description/Background
In 1992 the American Academy of Pediatrics made the recommendation that infants should sleep on their backs to reduce the risk of SIDS (Sudden Infant Death Syndrome), which launched the "Back to Sleep Campaign". Due to SIDS awareness through the Back to Sleep Campaign, the number of SIDS cases has decreased, but there has been a dramatic increase in the number of infants with positional plagiocephaly. In the majority of cases, having a flattened area will not affect a child’s brain growth or mental development. However, when unresolved flattening causes facial abnormalities, problems with chewing, eating, and vision may occur. If positional therapy does not work, helmet or band therapy may be recommended. For optimal effectiveness, it is recommended that helmet or band therapy begin by 5 (five) months of age. The length of therapy depends on the individual case, but usually takes between two and six months.

The original molding helmet was introduced in 1979, utilizing the basic concept of surrounding the asymmetrical infant head with a symmetrical (normal) mold. This helped the skull resume a normal shape. Dynamic Orthotic CranioplastySM (DOC Band®), was developed as an alternate approach for treating positional plagiocephaly. In this technique, the device was specifically designed to apply gentle pressure to the area of the head where growth was not wanted, while leaving space where growth was needed. The band was adjusted on a weekly or biweekly basis.

Craniosynostosis, on the other hand, is a premature fusion of one or more of the skull sutures which requires surgery to repair. A radiological examination is usually necessary to confirm the problem, characterize the deformity, and guide the corrective surgical procedure. Most experts recommend that babies undergo surgery between the ages of 3 (three) to 8 (eight) months, depending on the case and surgical procedure. Early intervention is beneficial for several reasons, aside from prevention of further deformities: the bones are most malleable at this age, bone re-growth is quicker and more likely, and rapid brain growth benefits from skull remodeling. Postoperative therapy may include the use of a cranial remolding orthosis.

**B. Specific Indications**

Cranial remolding orthoses are considered medically necessary for the following conditions when the listed criteria are met:

- Positional plagiocephaly (Non-synostotic plagiocephaly) with all of the following:
  1. The infant is between the ages of three to eighteen months of age when treatment is initiated; and
  2. The infant has undergone a two month trial of positioning therapy with clinical documentation of failure of improvement in symptoms; and
3. The infant has asymmetry in one of the following anthropometric dimensions:
   - Cranial vault; or
     - Cranial base; or
     - Orbitotrgial depth
   Or

4. The cephalic index measurement is one or two standard deviations (SD) from the mean (see Table 1)

OR

- Craniosynostosis with all of the following:
  1. The cranial remolding orthosis is being used in the post-operative treatment of this condition.
  2. The infant has asymmetry in one of the following anthropometric dimensions:
     - Cranial vault; or
     - Cranial base; or
     - Orbitotrgial depth
   Or
  3. The cephalic index measurement is one or two standard deviations (SD) from the mean (see Table 1)

Table 1:
Standard Deviation Table for Cephalic Index

<table>
<thead>
<tr>
<th>Age</th>
<th>-2 SD</th>
<th>-1 SD</th>
<th>MEAN</th>
<th>+1 SD</th>
<th>+2 SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male 16 days to 6 months</td>
<td>63.7</td>
<td>68.7</td>
<td>73.7</td>
<td>78.7</td>
<td>83.7</td>
</tr>
<tr>
<td>6-12 months</td>
<td>64.8</td>
<td>71.4</td>
<td>78.0</td>
<td>84.6</td>
<td>91.2</td>
</tr>
<tr>
<td>Female 16 days to 6 months</td>
<td>63.9</td>
<td>68.6</td>
<td>73.3</td>
<td>78.0</td>
<td>82.7</td>
</tr>
<tr>
<td>6-12 months</td>
<td>69.5</td>
<td>74.0</td>
<td>78.5</td>
<td>83.0</td>
<td>87.5</td>
</tr>
</tbody>
</table>

C. Limitations/Exclusions

1. Use of a cranial remolding orthosis is considered experimental-investigational and therefore not covered, when used as the sole treatment for craniosynostosis, which requires surgery to repair.
2. Use of a cranial remolding orthosis in an infant under three months of age who can benefit from intensive repositioning and stretching.
3. Infants with unmanaged hydrocephalus should be stabilized prior to beginning treatment with a cranial orthosis.

D. Information Required for Review

In order for medical necessity to be established, adequate information must be furnished by the treating physician. Necessary information includes the following:
1. A physician’s prescription or letter of medical necessity
2. Documentation supporting the member’s need for a cranial remolding orthosis must include:
   • The infant’s age and diagnosis
   • Clinical information from the treating physician confirming moderate to severe asymmetry of the cranial base
   • Evidence of two (2) month or longer trial of positioning therapy without improvement
3. Post-operative report when applicable

E. Review Process

1. The Medical Management Ancillary Service staff reviews the request according to review criteria. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member’s benefit plan.

F. Variations

N/A

G. Records Retention

Records Retention for documents, regardless of medium are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

H. Codes:

The following codes for treatments and procedures applicable to this policy 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.

Applicable CPT coding:

L0112 Cranial cervical orthotic, congenital torticollis type, with or without soft interface material, adjustable
L0113 Cranial cervical orthotic, torticollis type, with or without joint, with or without soft interface material
S1040 Cranial remolding orthotic, pediatric, rigid, with soft interface material, custom fabricated, includes fitting

I. References

Medical Literature/Clinical Information:
http://pediatrics.aappublications.org/content/114/4/970.full.pdf+html
http://pediatrics.aappublications.org/content/112/1/199.full.pdf+html

Regulatory/Government Sources:

Disclaimer:

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