UPMC Health Plan
POLICY AND PROCEDURE MANUAL

POLICY NUMBER: MP.017
REVISION DATE: 1/2009
ANNUAL APPROVAL DATE: 1/2009

SUBJECT: **Cranial Remolding Orthosis**
INDEX TITLE: **Medical Management**
ORIGINAL DATE: **March 2008**

This policy applies to the following lines of business: (Check those that apply.)

<table>
<tr><td colspan="6">Commercial:</td></tr>
<tr><td colspan="2">HMO ( )</td><td colspan="2">POS ( )</td><td>PPO ( )</td><td>OOA/DOC ( )</td></tr>
<tr><td colspan="2">Fully Insured ( )</td><td colspan="2">Self-funded/ASO ( )</td><td>HSA ( )</td><td>All (X)</td></tr>
<tr><td colspan="2">Medicare Select ( )</td><td colspan="2">Medicare Supplement ( )</td><td></td><td></td></tr>
<tr><td colspan="6">DPW-MA:</td></tr>
<tr><td colspan="3">Health Choices ( )</td><td colspan="2">Voluntary ( )</td><td>All (X)</td></tr>
<tr><td colspan="6">CMS-MA:</td></tr>
<tr><td>HMO (X)</td><td>PPO ( )</td><td>Specialty Needs Plan (X)</td><td>Part D ( )</td><td>PFFS (X)</td><td>All ( )</td></tr>
<tr><td colspan="6">PID-CHIP:</td></tr>
<tr><td colspan="3">Free ( )</td><td colspan="2">Sub ( )</td><td>All (X)</td></tr>
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I. POLICY

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

All denials are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director (Medical Director).

II. DEFINITIONS

N/A

III. PURPOSE

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

IV. SCOPE

This policy applies to various UPMC Health Plan 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

Asymmetry of the Orbitotragial Distances; at least a 4 mm right/left asymmetry measured from the lateral aspect of orbit to tip of ipsilateral tragus.

Cranial Remolding Orthosis (helmet or band) is a custom fitted device that is used in the treatment of non-synostotic plagiocephaly as a means to apply pressure to an infant's cranium to improve its shape or symmetry. 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.

Today there are a far wider variety of bands and helmets, many of which take into consideration the concepts of the original molding helmets and the DOC Band®. Every case is different, but all products are custom fit to the infant's head.

Cranial Vault Asymmetry: At least a 8 mm right/left discrepancy, measured from the frontozygomaticus point (identified by palpation of the suture line above the upper outer corner of the orbit) to the contralateral euryon, defined as the most lateral point on the head located in the parietal region.

Non-Synostotic Plagiocephaly (also known as Positional Plagiocephaly) refers to the condition of an asymmetric shaped head when the sutures are still open. The condition may be due to a variety of environmental factors including the infant's sleeping position, premature birth, or history of trauma at birth.

Plagiocephaly is an asymmetric condition of the head, due to irregular closure of the cranial sutures.

Positional Brachycephaly is when the entire back of the head is flat and the head has the appearance of being wide and short. Positional Brachycephaly is most often seen when a child sleeps entirely on the back of his head.

Positional Plagiocephaly (also known as Positional Head Deformity), is caused when repeated external pressure is applied to one side of the occiput (the back of the head) and a flat spot occurs. The term Positional is used to differentiate from true Synostosis and means there is NO premature suture fusion. Positional Head Deformity is the most common form of Positional Plagiocephaly.

Positional Scaphocephaly is when the head is long and narrow. Positional scaphocephaly can result when the infant is in a breech position during the pregnancy and the head becomes wedged underneath the mother's ribs. Prematurity can also be a contributing factor to positional scaphocephaly.

Positioning Therapy Technique:

- The infant is placed with their head turned to the opposite side of their flat spot. This can be achieved by placing a towel roll or rolled up blanket beneath the back and hip on the flattened side, positioning the baby to 45 degrees. Some physicians recommend using Velcro or tape to secure the roll to the infant's body.
- Place interesting objects on the opposite side of the bed to attract the infant's attention.
- When holding, feeding or carrying an infant, make sure that there is no undue pressure placed on the flat side of the head. Change infant's head position from side to side during feeding time.
- Provide the infant with plenty of supervised play time on his or her tummy. This helps build and strengthen neck, shoulder and arm muscles.

Skull Base Asymmetry: A right/left discrepancy (at least 6 mm) measured subnasally to the tip of the tragus (cartilaginous projection of the auricle at the front of the ear).

Synostosis –is the fusion of normally separate skeletal bones.

"True" Synostosis is a premature fusion of one or more of the skull sutures (Craniosynostosis) which requires surgery to repair.

B. Specific Indications

1. Cranial remolding orthosis is considered medically necessary when used in the treatment of non-synostotic plagiocephaly as a non-invasive method of correcting moderate to severe positional head deformities due to:
   - Birth trauma,
   - Premature birth,
   - Sleeping positions,
   - Restrictive intrauterine positioning,
   - Cervical abnormalities and torticollis.

   AND
   When all of the following criteria are met:
   - The infant is between the ages of three (3) to eighteen (18) months of age when treatment is initiated, and
   - The infant has undergone a trial of positioning therapy for duration of at least two (2) months with clinical documentation of failure of improvement in symptoms, and
   - The infant has asymmetry of the cranial base as documented by any one of the following:

- Skull Base Asymmetry, or
- Cranial Vault Asymmetry, or
- Asymmetry of the Orbitotragial Distances.

2. Cranial remolding orthosis used in the post-operative treatment of synostotic plagiocephaly are considered medically necessary for infants with moderate to severe residual plagiocephaly after surgical correction.

C. Limitations

Cranial helmeting or banding is experimental-investigational as the sole treatment for synostosis (aka; "true synostosis") which requires surgery to repair.

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 orthoses (helmet or band) must include:
    1. The infant's age and diagnosis;
    2. Clinical information from the treating physician confirming moderate to severe asymmetry of the cranial base;
    3. Evidence of two (2) month or longer trial of positioning therapy and symptoms has failed to improve.
3. Post operative report when necessary.

E. Review Process

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to a UPMC Health Plan 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 member's benefit.

F. Variations

N/A

Proprietary and Confidential Information of UPMC Health Plan

G. References

1. Ian F. Pollack, H. Wolfgang Losken, and Patricia Fasick. Diagnosis and Management of Posterior Plagiocephaly, University of Pittsburgh Publisher Pediatrics Vol. 99 No. 2 February 1997, pp. 180-185. http://pediatrics.aappublications.org/cgi/content/abstract/99/2/180
2. Craniosynostosis and Positional Plagiocephaly Support, Positional Plagiocephaly Frequently Asked Questions. http://www.cappskids.org/PlagioFAQ.htm
3. American Association of Neurological Surgeons, Neurosurgery Today.org, What is Neurosurgery, Positional Plagiocephaly, September, 2005. http://www.neurosurgerytoday.org/what/patient_e/positional_plagiocephaly.asp
4. National Library of Medicine. Medical Encyclopedia, Cranial Sutures. http://www.nlm.nih.gov/medlineplus/ency/article/002320.htm.
5. Hutchison BL, Hutchison LA, Thompson JM, Mitchell EA. Plagiocephaly and brachycephaly in the first two years of life: a prospective cohort study. Pediatrics. 2004; 114(4):970-80.
6. Persing J, James H, Swanson J, Kattwinkel J. American Academy of Pediatrics Committee on Practice and Ambulatory Medicine, Section on Plastic Surgery and Section on Neurological Surgery. Prevention and Management of Positional Skull Deformities in Infants. Pediatrics. 2003; 112(1 Pt 1):199-202.
7. Unicare Medical Policy, Adjustable Band for the Treatment of Non-Synostotic Plagiocephaly and Brachycephaly, Infants, Policy #: OR-PR.00002, Effective 2/5/07. http://medpolicy.unicare.com/policies/OR-PR/cranial_orthosis.html
8. Graham J, Kreutzman J. Deformational Brachycephaly in Supine-Sleeping Infants. Journal of Pediatrics. 2005; 254-257.
9. Joseph E. Losee, M.D., FACS, FAAP [a, b], A. Corde Mason, M.D., FAAP [a], Elsevier Saunders, Clinics in Plastic Surgery, Deformational plagiocephaly: diagnosis, prevention and treatment, Circa Plastic Surg 32 (2005), 53-64.

Disclaimer:

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