

OHCA Guideline

Medical Procedure Class:	Cranial Remolding Orthosis (Helmet)
Initial Implementation Date:	1/1/2020
Last Review Date:	N/A
Effective Date:	2/21/2020
Next Review/Revision Date:	2/21/2023
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input checked="" type="checkbox"/> New Criteria <input type="checkbox"/> Revision of Existing Criteria	
Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
Definitions	
<p>Craniosynostosis: Premature closure of one or more sutures of the skull. Craniosynostosis is a non-positional cause of abnormal head shape in infants and occurs when one or more of the sutures in the infant's skull fuse prematurely. The premature fusion of one or more sutures puts pressure on the brain, potentially restricting brain growth and exerting pressure on the other skull bones to expand out of proportion, leading to abnormal skull shape. This can result in neurologic damage and progressive craniofacial distortion.</p> <p>Plagiocephaly: Flattening of one side of the skull producing an asymmetrically shaped head. Plagiocephaly is most often the result of an infant spending extended periods of time on their back, typically during sleep. Plagiocephaly can also occur as a feature of other disorders (e.g., craniofacial disorders, torticollis, and cervical anomalies) and is categorized as either positional or non-positional (premature union of cranial sutures).</p> <p>Positional Plagiocephaly: An acquired flattening of the skull of an infant, usually after repeatedly sleeping in a single position (e.g., on the infant's back, to prevent Sudden Infant Death Syndrome (SIDS)). Also referred to as deformational Plagiocephaly, it can usually be treated nonoperatively by repositioning the developing infant frequently, or by having the child wear a protective, adjustable helmet while resting.</p> <p>Severe Plagiocephaly: An asymmetry of 10 mm or more in one of the following Anthropometric Measurements: cranial vault, skull base, or orbitotragial depth; or a Cephalic Index of at least 2 standard deviations above or below the mean for the appropriate gender/age.</p>	
Description	
<p>Cranial Remolding Orthosis – rigid, custom-fabricated/fitted/molded headband or helmet that is designed to actively guide the growth of the skull to a more normal shape. It allows for growth in certain regions of the cranium and restricts growth in others. They do not alter the magnitude of intrinsic brain growth but rather its direction. Symmetrical growth is achieved by consistent evaluation and adjustments to the orthosis based on the child's head shape and growth patterns.</p>	
HCPCS Code Covered Requiring Prior Authorization (PA)	
S1040 (See HCPCS manual for code definitions)	

Approval Criteria

A cranial remolding orthosis will be considered medically necessary when either of the following criteria are met:

1. Craniosynostosis, following endoscopic surgical correction; or
2. Craniofacial asymmetry with SEVERE (non-synostotic) positional plagiocephaly when **ALL** of the following criteria are met:
 - a. Infant between 3-18 months of age
 - b. Severe plagiocephaly is present with or without torticollis
 - c. Documentation of a trial of conservative therapy of at least 2 months duration with cranial repositioning, with or without stretching therapy.

*Cranial orthotic devices used for treating infants with mild to moderate plagiocephaly do not improve physiologic function and are considered cosmetic.

Additional Information

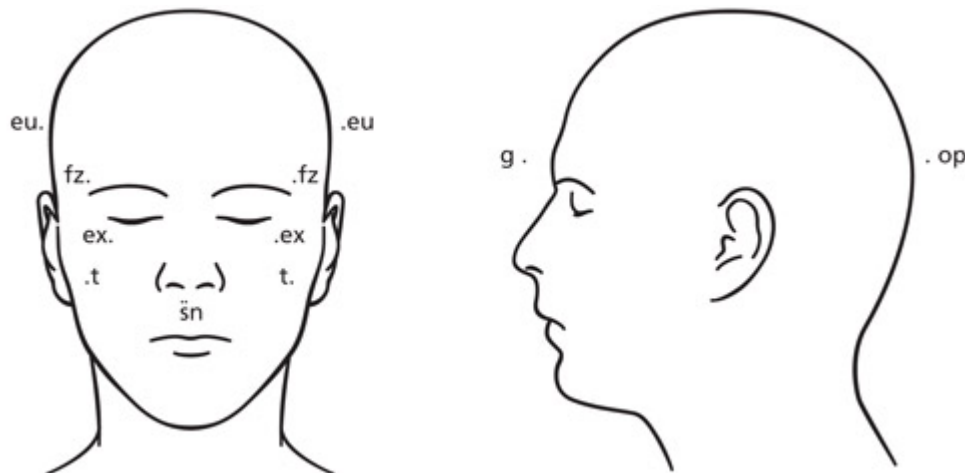
Evaluation of Plagiocephaly

The diagnosis of the type of craniosynostosis is confirmed through physical examination and imaging studies.

Anthropometric data, or the measurements used to evaluate abnormal head shape by measuring the distance in millimeters from one pre-designated point on the face or skull to another, must document severe plagiocephaly. (A difference in 10 mm between anthropometric measurements signifies severe plagiocephaly.)

The evaluation of cranial asymmetry may be based on 1 or more of 4 anthropometric measures: cranial vault, skull base, orbitotragial depth measurements or the cephalic index.

Anthropometric Data	Measurement	Measures
Cranial base (sn-t on same side)	from right and left subnasal point (sn) to tragus (t)	measures maxillary depth or right and left morphological face height
Cranial vault (fz R-euL, fz L-euR)	from frontozygomatic 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 orbito-tragion depth (exocanthion)



Evaluation of cranial asymmetry may also be based on the Cephalic Index, a ratio between the width and length of the head.

- Head width is typically calculated by subtracting the distance from euryon (eu) on one side of the head to euryon on the other side of head and multiplying by 100.
- Head length is generally calculated by measuring the distance from glabella point (g) to opisthocranion point (op).

$$\text{Cephalic index} = \frac{\text{Head width (eu - eu)} \times 100}{\text{Head length (g - op)}}$$

The Cephalic Index is considered abnormal if it is 2 standard deviations above or below the mean measurements.

Sex	Age	-2 SD	-1 SD	Mean	+1 SD	+2 SD
Male	16 days to 6 months	63.7	68.7	73.7	78.7	83.7
Male	6 to 18 months	64.8	71.4	78	84.6	91.2
Female	16 days to 6 months	63.9	68.6	73.3	78	82.7
Female	6 to 18 months	69.5	74	78.5	83	87.5

References

1. Oklahoma Health Care Authority policy OAC 317:30-3-1 and 317:30-5-211.2
2. Congress of Neurological Surgeons, Evidence Based Guidelines for the Treatment of Pediatric Positional Plagiocephaly,
3. Aetna, Medical Clinical Policy Bulletin, Number 0379: Cranial Remodeling, 07/16/2019.
4. United Healthcare, Policy number 2019T0031R, Plagiocephaly and Craniosynostosis Treatment, 10/1/2019.