

Medical Coverage Policy

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Service/Device

The cranial band or helmet is used to correct asymmetry of the cranium and face.

The device is durable medical equipment requiring clinical review by a Utilization Management Physician.

II. Clinical Indications

The use of a cranial remodeling band or helmet is considered medically necessary for the treatment of:

- **A.** Synostotic plagiocephaly following surgical correction.
- **B.** Moderate to severe positional head deformities associated with premature birth, restrictive intrauterine positioning, cervical abnormalities, birth trauma, torticollis (shortening of the sternocleidomastoid muscle) and sleeping positions in infants when banding is initiated at 4 to 12 months of age and the following conditions are met:
 - 1. The child has failed to respond to a 2- month trial of repositioning therapy between the ages of 2 and 5 months.
 - **2.** There is documentation of either of the following 2(a) or 2(b)criteria:
 - a. Asymmetry of 10 mm or more in one of the following measures (see diagram and table 1 below):
 - (1) cranial vault (fz R-euL, fz L-euR)
 - (2) cranial base (sn-t on same side)
 - (3) orbitotragial depth (ex-t, R, L)
 - b. Cephalic index + at least 2 standard deviations from the mean for the appropriate gender/age (see table 2 below).



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Diagram and Measurements

For evaluating the degree of positional head deformities listed in II. B. 2

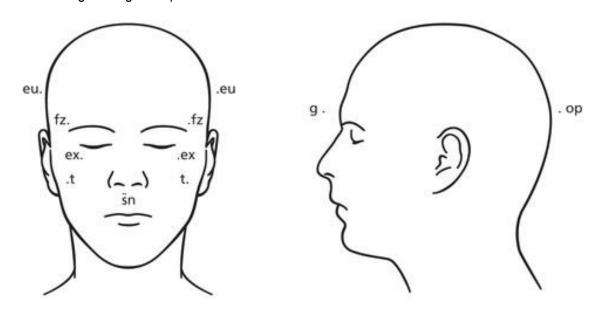


Table 1: Symmetry

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 frontozygomaticus 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)	

Cephalic index = [Head width (eu - eu) x 100] \div [Head length (g - op)]

Table 2: Cephalic index

Sex	Age	-2SD	-1SD	Mean	+1SD	+2SD
Male	16 days to 6 months	63.7	68.7	73.7	78.7	83.7
	6 - 12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days to 6 months	63.9	68.6	73.3	78.0	82.7
	6 - 12 months	69.5	74.0	78.5	83.0	87.5



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III. Usage Guideline

- A. These devices may be dynamic, compressing the prominent part of the skull, or passive, allowing growth only in the flattened part of the skull. They are worn 15–22 hours a day, and length of treatment depends on the infant's age, the severity of the asymmetry, and compliance with the treatment regimen.
- **B.** Treatment is most effective when begun during the first year of life, when brain growth is most rapid.
- C. For very young infants, (8 months or younger), a second orthosis may be medically necessary to prevent regression of head shape in very young infants who met the criteria in Section II at the initiation of therapy, who have outgrown the initial orthosis, and have not developed midline head control, rolling, or sitting. A second orthosis may also be medically necessary if the asymmetry has not significantly improved, and criteria as listed are met after 2 to 4 months of treatment.
 - **D.** Covered services include device and related office visits for measurement and fitting

IV. Contraindications / Limitations

- **A.** Cranial remodeling bands or helmets are contraindicated and considered not medically necessary after 2 years of age).
- **B.** Cranial remodeling bands or helmets are considered experimental and investigational for conditions not meeting the criteria in section **II.**
- **C.** The use of cranial remodeling bands or helmets without surgery to correct asymmetry in infants with synostotic plagiocephaly is considered experimental and investigational.



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Approval History

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	State of Maryland	(Ten days after filing)	
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Approval History

Effective June 01, 2016, state filing no longer required per Maryland House Bill HB 798 - Health Insurance - Reporting

Date approved by RUMC	Date of Implementation
04/25/2017	04/26/2017
04/27/2018	04/27/2018
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02/17/2021	02/17/2021
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02/22/2023	02/22/2023
02/21/2024	02/21/2024

^{*}The Regional Utilization Management Committee received delegated authority to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee in 2011.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

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