



Cranial Remodeling Orthotic Devices

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

Guideline Name: Cranial Remodeling Orthotic Devices - Single Service

Literature review current through: 11/17/2023

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Type: Adult (18+ yo) | Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Cranial Remodeling Orthotic Devices

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Cranial remodeling orthotic devices apply pressure to prominent skull regions to improve cranial symmetry in infants with moderate to severe non-synostotic positional plagiocephaly.
- **Exclusions:** Children older than 18 months of age and infants with head deformities due to uncorrected craniosynostosis or hydrocephalus.

Medical Necessity Criteria

Indications

→ **Cranial Remodeling Orthotic Devices** are considered appropriate if **ANY** of the following is **TRUE**:

- ◆ For initial use as indicated by **ANY** of the following:
 - Craniosynostosis surgery has been performed¹⁻³; **OR**
 - Positional plagiocephaly or brachycephaly when indicated by **ALL** of the following:⁴⁻⁵
 - Age 18 months or younger⁶⁻⁸; **AND**
 - **ANY** of the following:
 - ◆ Two month trial of repositioning or physical therapy has not produced a favorable response; **OR**
 - ◆ Favorable response to repositioning or physical therapy is not expected due to the severity of the deformity (two standard deviations or more above or below the mean cranial index for age and gender)⁹; **AND**
 - The provider has determined that the child is a good candidate for helmet therapy, and the caregiver and provider have both agreed that the child can tolerate a daily wearing program of 23 hours; **AND**
 - Confirmation and treatment of known underlying neuromuscular influencers (if applicable); **AND** ¹⁰⁻¹¹

- Moderate to severe deformity confirmed by anthropometric assessment confirms and **ANY** of the following is **TRUE**:¹²
 - ◆ Cephalic index of 90% or more^{10,13}; **OR**
 - ◆ Cranium difference in diagonal diameters is 1.0 cm or more¹⁰; **OR**
- ◆ Additional requests to accommodate growth changes when **ALL** of the following are **TRUE**:
 - Patient is between six and eighteen months of age; **AND**
 - Continued use of orthoses needed for additional cranial asymmetry correction; **AND**
 - Unsuccessful treatment with **ANY** of the following:
 - At least two months of home management for infants without cervical motion restriction; **OR**
 - Physical therapy or home exercise program for infants with cervical motion restriction; **AND**
 - A new orthoses may be required when documentation indicates that the current device is insufficient (e.g., skin complications, inadequate therapeutic positioning due to head growth).

Non-Indications

- **Cranial Remodeling Orthotic Devices** are not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ For children older than 18 months of age; **OR**
 - ◆ For infants with head deformities due to uncorrected craniosynostosis or hydrocephalus.

Level of Care Criteria

Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS/CPT Code	Code Description
L0112	Cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
L0113	Cranial cervical orthosis, torticollis type, with or without joint, with or without soft interface material, prefabricated, includes fitting and adjustment
S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes

	fitting and adjustment(s)
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Medical Evidence

Santiago et al. (2023) provide a report on the management and treatment of positional plagiocephaly and craniosynostosis. The ideal age for orthotic helmet use is between age four and eight months of age, as fontanelle closure is between nine and 12 months of age. The length of orthotic helmet use depends on the degree of asymmetry (typically three to six months duration, stopping use after 12 months of age). Efficacy rates are high – helmet therapy was successful in 94.4% of infants who used helmet therapy as a first-line therapy; helmet use after unsuccessful conservative therapy was successful in 96.1% of infants.⁸

Graham et al. (2019a) performed a retrospective review to determine factors that influence the efficacy of cranial remolding orthoses in infants with deformational plagiocephaly. Research demonstrates that outcomes are more favorable among younger infants. A total of 499 patients were in the review. Age at diagnosis, presenting severity, and the presence of torticollis factor in the length of time that orthoses are needed. Study limitations include the inability to control patient education, which could positively impact patient compliance.⁶

National and Professional Organizations

The American Academy of Pediatrics (AAP) published a clinical report on craniosynostosis and related disorders. An overview is provided of head shape abnormalities, related disorders, and treatment options (including helmet therapy).¹⁴

The Congress of Neurological Surgeons (CNS) published a 2016 guideline for treating pediatric positional plagiocephaly. Repositioning is the preferred treatment for deformational plagiocephaly. Evidence demonstrates that repositioning is inferior to physical therapy and the use of a helmet, respectively.¹⁵ A second guideline is available on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. Helmet therapy is for infants with “persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy)...[and] moderate to severe plagiocephaly presenting at an advanced age.”⁹

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