

Subject: Cranial Orthotic Devices for the Treatment of Positional Cranial Deformity*	Original Effective Date: 10/11/07
Guidance Number: MCG - 041	Revision Date(s): 2/10/11, 9/23/14

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Cranial orthotic devices (CODs), also referred to as cranial helmets, cranial orthoses, and cranial bands, are prefabricated or custom-fitted and custom-molded devices are used to redirect growth of the skull bones and reduce cranial asymmetry in infants who have positional cranial deformity. CODs allow for growth in certain regions of the cranium and restrict growth in others. Designs may be active or passive in nature, rigid or flexible, or hinged or circumferential. To encourage the skull to grow into a desired configuration, most helmets apply passive restriction rather than active compression forces. Construction of the COD is based on a cast or 3-dimensional image of the infant’s head. The model is modified to full or partial symmetry, depending on the severity of the condition, design of the orthosis, and protocols of the treating orthotist. Mild or moderate asymmetries may be modified to full symmetry while severe deformations may require progressive adjustments to the inner surface of the CODs to obtain full symmetry throughout the course of the treatment program. Symmetrical growth is achieved by consistent evaluation and adjustments to the COD based on the child’s head shape and growth patterns. Circumferential growth is accommodated by the addition, removal, or recontouring of material to ensure total contact over prominent areas, provide relief over depressed areas, and stabilize the COD on the infant’s head. Generally, infants aged 4 to 6 months will require 10 to 16 weeks of treatment with evaluation every 2 to 3 weeks. Older infants generally require a longer treatment program due to slower cranial growth toward the end of their first year. Discontinuation of treatment occurs at the discretion of the medical team and the family when a desirable degree of symmetry or improvement is obtained.³

There are 2 components of cranial deformity: plagiocephaly and brachycephaly. Plagiocephaly refers to an asymmetrical, flattened deformity of the skull that often presents with ipsilateral frontal bossing of the forehead and anterior shift of the ipsilateral ear (ear deviation) and cheek. Brachycephaly refers to symmetrical occipital flattening of the skull that can be accompanied by temporal bossing or an occipital lift. Non-synostotic plagiocephaly (NSP) (also referred to as deformational or positional plagiocephaly) is the most common cranial deformity condition in infants.³

RECOMMENDATION

Cranial orthotic devices for the treatment of infants and children with positional plagiocephaly is considered investigational, experimental and unproven due to insufficient evidence in the peer reviewed medical literature.

***NOTE:** All requests for cranial orthotic devices for the diagnosis of craniosynostosis may be reviewed with the McKesson InterQual DME Cranial Orthoses Criteria set.

SUMMARY OF MEDICAL EVIDENCE

There is insufficient evidence to support that cranial orthotic devices are effective in the treatment of infants and children with positional plagiocephaly. The overall quality of evidence is low and consists of one randomized controlled trial that reported no difference between COD treatment and natural course observation (between-group difference, 0.2%; P=0.80). This study also reported no significant between-group differences in parental satisfaction ratings, motor development, and quality of life.⁴ The rest of the published evidence consists of prospective nonrandomized controlled studies, prospective cohort studies, case-control and retrospective cohort studies.⁵⁻¹³ Across these studies, study populations ranged from 69 to 298. The mean age at initiation of treatment ranged from 2 months to 37.5 weeks. The mean duration of treatment ranged from 2 to 48.2 months. The observational studies reported equal or better outcomes for COD compared with repositioning;⁵⁻¹³ however, the RCT did not find a difference in outcomes between COD and observation.⁴

The only randomised controlled trial (HEADS, HELmet therapy Assessment in Deformed Skulls) was conducted to determine the effectiveness of helmet therapy for positional skull deformation compared with the natural course of the condition in infants aged 5-6 months. Participants included 84 infants aged 5 to 6 months with moderate to severe skull deformation, who were born after 36 weeks of gestation and had no muscular torticollis, craniosynostosis, or dysmorphic features. Infants were randomly assigned to helmet therapy (n=42) or to natural course of the condition (n=42) according to a randomisation plan with blocks of eight. Six months of helmet therapy compared with the natural course of skull deformation were monitored. The primary outcome was change in skull shape from baseline to 24 months of age assessed using plagiocephalometry (anthropometric measurement instrument). Change scores for plagiocephaly (oblique diameter difference index) and brachycephaly (cranioproportional index) were each included in an analysis of covariance, using baseline values as the covariate. Secondary outcomes were ear deviation, facial asymmetry, occipital lift, and motor development in the infant, quality of life (infant and parent measures), and parental satisfaction and anxiety. Baseline measurements were performed in infants aged between 5 and 6 months, with follow-up measurements at 8, 12, and 24 months. Primary outcome assessment at 24 months was blinded. The results showed that the change score for both plagiocephaly and brachycephaly was equal between the helmet therapy and natural course groups, with a mean difference of -0.2 (95% confidence interval -1.6 to 1.2, P=0.80) and 0.2 (-1.7 to 2.2, P=0.81), respectively. Full recovery was achieved in 10 of 39 (26%) participants in the helmet therapy group and 9 of 40 (23%) participants in the natural course group (odds ratio 1.2, 95% confidence interval 0.4 to 3.3, P=0.74). All parents reported one or more side effects. Based on the equal effectiveness of helmet therapy and skull deformation following its natural course, high prevalence of side effects, and high costs associated with helmet therapy, we discourage the use of a helmet as a standard treatment for healthy infants with moderate to severe skull deformation.⁴

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CPT	Description
	N/A

HCPCS	Description
L0112	Cranial cervical orthotic, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
L0113	Cranial cervical orthotic, 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)
ICD-9	Description
754.0	Certain congenital musculoskeletal deformities, of skull, face, and jaw
ICD-10	Description
Q67.3	Plagiocephaly

RESOURCE REFERENCES

1. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). 501(k) Premarket Notification Database. Cranial orthosis. Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN.pmn.cfm>.
2. Centers for Medicare & Medicaid Services (CS). Medicare Coverage Database. National Coverage documents. Accessed at: <http://www.cms.hhs.gov/mcd/search.asp>
3. Hayes Medical Technology Directory. Cranial Orthotic Devices for the Treatment of Positional Cranial Deformity. Winifred Hayes Inc. Lansdale, PA. July 17, 2014.
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DISCLAIMER

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CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members.