

Subject: Cranial Orthotic Devices		Original Effective Date: 10/11/07
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. 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 Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL ³

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 when a desirable degree of symmetry or improvement is obtained.

Craniosynostosis is a medical condition in which some or all of the sutures in the skull of an infant close prematurely. Craniosynostosis can be differentiated from plagiocephaly as it is consistently present at birth and is progressive. It will not improve spontaneously and has a risk of developing increased intracranial pressure. Craniosynostosis often requires surgical intervention as plagiocephaly does not. Plagiocephaly is a cephalic disorder and is commonly characterized by an asymmetrical distortion (flattening of one side) of the skull. Plagiocephaly is usually not present at birth, develops within the first few months of life, and does not have a risk of intracranial pressure. Positional plagiocephaly is treated conservatively and many cases do not require any treatment as the condition may resolve spontaneously when the infant begins to sit up. When the deformity is moderate or severe and a trial of re-positioning, stretching, and/or physical therapy has failed, a pediatric specialist in craniofacial deformities may prescribe a cranial remodeling helmet to improve cranial symmetry or shape of the head.

There are 3 components of cranial deformity: positional plagiocephaly (abnormal cranial vault asymmetry index), positional brachycephaly (abnormal cranial index) and combined positional plagiocephaly and brachycephaly (abnormal cranial vault asymmetry index and cranial index). 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. Using the cranial vault asymmetry measure (difference between the diagonal calliper measures), a difference of >10-12 mm is described as severe. An abnormal cephalic index (CI) is identified when there are 2 standard deviations (SD) above or below the mean measurements. However, literature is inconclusive for a standardized definition of severity ranges.

TABLE 1 Cranial Asymmetry Measurements*

Anthropometric Data	Measurement	Measures
Skull base	From right and left subnasal point to tragus	Right and left morphological face height and maxillary depth
Cranial Vault	Left frontozygomatic point to right euryon	Cranial Vault asymmetry
Orbitotragial Depth	Exocanthion point to left tragus	Orbito-tragion depth

TABLE 2 Cranial Index (CI) measurements*

Gender	Age	-2 SD	-1SD	Mean	+1SD	+2SD
Male	16 Days to 6 months	63.7	68.7	73.7	78.7	83.7
	6 to 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 to 12 months	69.5	74.0	78.5	83.0	87.5

RECOMMENDATION 4-28 29 31-32**Nonsynostotic Positional Plagiocephaly Criteria**

1. Cranial orthotic devices **are considered medically necessary** in infants with severe nonsynostotic positional plagiocephaly when all of the following criteria have been met:

- Age for initiation of therapy is between 3-12 months; and
- Has failed to respond to a 2 to 3 month trial of repositioning therapy and physical therapy if torticollis is also present; and
- Documentation of severe asymmetry as evidenced by one of the following criteria: [ONE]
 - Asymmetry of > 10-12mm in cranial vault, skull base or orbitotragial depth as referenced Table 1 above*; or
 - Cephalic index of at least ± 2 standard deviations from the mean as referenced in Table 2 above*

AND all of the Following documentation is submitted: [ALL]

- Complete history and physical assessment with physician and consultation notes describing the plagiocephaly; and
- Imaging only when clinical diagnosis is equivocal; and
- Cranial asymmetry measurements supporting the requirements listed above by a qualified physician or technician; and
- Photograph of the deformity as available; and
- Documentation supporting the family education and treatment time of repositioning techniques and physical therapy, when appropriate

Craniosynostosis Criteria:

2. Cranial orthotic devices for the diagnosis of craniosynostosis **are considered medically necessary** for infants with synostotic plagiocephaly to correct continued asymmetry following surgery.

EXCLUSIONS

3. Cranial orthotic devices **initiated** for infants who are < 3 months of age or >12 months of age are considered not medically necessary.
4. Cranial orthotic devices are not medically necessary and contraindicated in patients with untreated/unshunted hydrocephalus and in patients with uncorrected craniosynostosis.

SUMMARY OF MEDICAL EVIDENCE 4-28

The use of COD's is controversial and there is conflicting 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 or find a

difference in outcomes between COD and observation.²⁷ The rest of the published evidence consists of systematic reviews, prospective nonrandomized controlled studies, prospective cohort studies, case-control and retrospective cohort studies, case series, observational studies and reviews. Across these studies, participants 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. These studies generally reported equal or better outcomes for COD compared with repositioning. Despite conflicting evidence, the management of positional plagiocephaly in infants using conservative therapy (repositioning and physical therapy) for the treatment of mild/moderate deformity in younger infants and reserving helmet therapy for more severe deformity has become standard of care in the medical community.

The only randomized 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.²⁷

Paquereau J. (2013) conducted a systematic review of 11 cohort studies and 6 literature reviews that concluded orthotics seem to correct head deformities in patients with moderate to severe posterior positional plagiocephaly better and faster than repositioning protocols, especially when treatment is initiated before the age of 1 year, although evaluation methods, treatment indications, and long-term efficacy should be better defined.²¹

Steinberg et al. (2015) performed a retrospective cohort study of 4378 infants with deformational plagiocephaly and/or deformational brachycephaly found that conservative measures alone resulted in 92% complete correction at 18 months, and that helmet therapy (including 534 infants originally treated with conservative

measures) resulted in 95% complete correction. The authors concluded that delaying helmet therapy for a trial of conservative measures did not preclude complete correction, particularly if the patient was younger than 9 months of age and was adherent to therapy. ²⁶

Professional Society Guidelines ²⁹

Congress of Neurological Surgeons: Systematic Review and Evidence-Based Guideline on the Role of Cranial Molding Orthosis (Helmet) Therapy for Patients With Positional Plagiocephaly (2016). The purpose of this review was to address if helmet therapy provide effective treatment for positional plagiocephaly and to make treatment recommendations based on the available evidence. Fifteen articles met criteria for inclusion into the evidence tables. There was 1 prospective randomized controlled trial (Class II), 5 prospective comparative studies (Class II), and 9 retrospective comparative studies (ClassII). There is a fairly substantive body of non-randomized evidence that demonstrates more significant and faster improvement of cranial asymmetry in infants with positional plagiocephaly treated with a helmet as compared to conservative therapy, especially if the asymmetry is severe, and provided that helmet therapy is applied during the appropriate period of infancy. As outlined above, specific criteria regarding the measurement and quantification of deformity and the most appropriate time window in infancy for treatment of positional plagiocephaly with a helmet remain elusive. In general, infants with a more severe presenting deformity and infants who are helmeted early in infancy tend to have better correction (and even normalization) of head shape. The only randomized study pertaining to this recommendation provided data that showed no benefit of helmet therapy in the treatment of positional plagiocephaly in infants. Issues with the design and execution of this study may explain why the randomized data conflicts with the majority of the non-randomized evidence.

In summary the guidelines recommend physical therapy and repositioning early in the process and cranial orthosis for refractory cases defined as:

- Helmet therapy for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy). Strength of Recommendation: Level II
- Helmet therapy is recommended for infants with moderate to severe plagiocephaly presenting at an advanced age. Strength of Recommendation: Level II

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A
HCPCS	Description
S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)
L0112	Cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
ICD-10	Description: [For dates of service on or after 10/01/2015]

Q67.3	Plagiocephaly
Q67.4	Other congenital deformities of skull, face and jaw
Q75.8-Q75.9	Other specified congenital malformations of skull and face bones

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Revision History:

10/11/07: New Policy

2/10/11, 9/23/14: Policy reviewed and revised.

12/16/15, 9/15/16 & 9/19/17: Policy reviewed, no changes to criteria.

7/10/18: This policy was reviewed and the clinical criteria has changed based on new evidence based literature and updated professional society guidelines. COD's were previously considered I/E. There is an abundance of literature published and updated guidelines that consider COD's standard of care for the treatment of non-synostotic positional plagiocephaly and for infants with synostotic plagiocephaly to correct continued asymmetry following surgery when certain criteria are met. The following sections were also updated: summary of medical evidence, professional society guidelines and references.

9/18/19: Policy reviewed, no changes to criteria.