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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. Craniosyntosis 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 29-37]

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 (i.e. corrected age for premature infants); 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/LIMITATIONS

- ❑ Cranial orthotic devices ***initiated*** for infants who are < 3 months of age or >12 months of age are considered not medically necessary.

- ❑ Cranial orthotic devices are not medically necessary and contraindicated in patients with untreated/unshunted hydrocephalus and in patients with uncorrected craniosynostosis.

CONTINUATION OF THERAPY

N/A

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. [4-28] The optimal age has not been defined well in the literature as to the role of initiating COD's for positional plagiocephaly. Professional Society Guidelines and current literature indicate that the efficacy of asymmetry reduction decreased with increasing age and the average duration of treatment increased with older ages. [29-37]

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. According to this study "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 (craniproportional 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]

Han et al.; (2017) investigated the optimal age for starting cranial-remolding-orthosis therapy in children with deformational plagiocephaly in a retrospective review. According to this study "Medical records of 310 patients with deformational plagiocephaly were retrospectively reviewed and the initial and final cranial vault asymmetry index (CVAI), age when starting therapy, duration of therapy, mean change of CVAI, improvement rate, and treatment success were analyzed. We compared outcomes according to the groups divided by ages starting therapy.There were no significant differences in improvement rate and duration of cranial-remolding-orthosis therapy among patients starting therapy at the age of 3, 4, and 5 months. However, when starting therapy after the age of 6 months, the rates of CVAI improvement were significantly lower and the duration of therapy was significantly increased." The authors concluded that, "considering the spontaneous resolution effect according to the head growth nature, the age 5 month is the optimal period to start cranial-remolding-orthosis therapy for deformational plagiocephaly." [33]

Grahm et al.; (2019 A & B) performed a retrospective chart review to assess clinical findings about the influence of certain intake factors on treatment outcomes of CROs. Specifically, this study aims to examine the statistical effect of a patient's initial deformational severity, age of initiation of CRO treatment, presence or absence of torticollis, and presence or absence of prematurity on the outcome of a patient's CRO treatment. The outcome measures of orthotic treatment being examined in this study are total CRO treatment time and final head shape. According to this study "Of the 2,423 charts reviewed, 499 patients were found to meet the inclusion criteria and had complete data for analysis. The results of this study suggest that infants have better treatment outcomes when they are younger, less severe, and without torticollis; however, a longer treatment duration was shown to be successful for patients with torticollis. Since CRO initiation age strongly influences an infant's rate of correction, parents of older infants should be counseled regarding treatment expectations and understand treatment duration may be substantially longer for older infants. Because the FDA recommends CRO's to be used only for infants from 3–18 months of age; older infants with more severe deformations might not be able to achieve the desired cranial correction due to their decreased rate of change of CVAI. Further studies are needed to determine if there is a "cut-off" age at which older infants are unlikely to benefit from a CRO." [32]

Cevik et al.; (2020) investigated the effect of age at helmet therapy onset on treatment efficacy in moderate-to-severe deformational plagiocephaly (DP) and combined DP and asymmetrical brachycephaly (AB) in infants. According to this study "Ninety-eight infants who were referred to our institution and who underwent helmet therapy between 2014 and 2018 were retrospectively reviewed. Patients with DP [cranial vault asymmetry index (CVAI) > 7% and DD > 10 mm] and AB [CVAI > 7% and cephalic ratio (CR) ≥ 94] were included. Pre- and post-treatment calvarial asymmetries (difference among DD, CVAI, and CR) were measured using 3D screening systems (SmartSoc and Omega Scanner 3D). Infants were classified according to age at treatment onset: group 1 (age, < 6 months) and group 2 (age, ≥ 6 months). CVAI was statistically different between treatment onset and end in subgroups. Moreover, the regression of CVAI between groups DP1 (- 7.5% ± 1.2%) versus DP2 (- 5.4% ± 1.5%; p = 0.001) and groups AB1 (- 6.6% ± 1.4%) versus AB2 (- 4.4 ± 2.5; p = 0.0013) was statistically significant. CVAI was < 3.5% and CR was ≤ 89 (assumed as normal cranial shape) after treatment in 48%, 40%, 32%, and 6% of infants in groups DP1, DP2, AB1, and AB2, respectively. The authors concluded that these findings emphasize the efficacy of helmet therapy for DP and AB. Helmet is an appropriate treatment option particularly for infants with severe DP and AB, and early onset of helmet therapy before the age of 6 months is advised." [29]

Professional Society Guidelines [37]

Congress of Neurological Surgeons (CNS): Systematic Review and Evidence-Based Guideline on the Role of Cranial Molding Orthosis (Helmet) Therapy for Patients With Positional Plagiocephaly (2016). According to the CNS guidelines "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."

Age at Initiation of Helmet Therapy and Outcome [37]

According to the CNS guidelines, "Two prospective studies serve to clarify the relationship between age at initiation of helmet therapy and treatment outcomes that was suggested by some of the methodologically weaker retrospective studies.36,38 Both studies examined patients with "significant" cranial asymmetry who appear not to have undergone any prior conservative treatment. The results of both studies were similar, although the recommended age cut-off between those infants who were expected to achieve a satisfactory treatment response and those expected to have a suboptimal response was slightly different between the two studies":

- Seruya et al (prospective comparative study) assessed the results of custom helmet therapy in 346 patients in 7 pre-defined age groups ranging from <20 weeks to >40 weeks. The degree of calvarial asymmetry was similar in all groups at the beginning of therapy. They found that all patients achieved normal calvarial symmetry at the end of helmet therapy, except those helmeted at >36 weeks of age. Improvement was seen even in infants aged >12 months at time of helmet therapy initiation. Duration of helmet therapy was positively correlated with age. [31]

- Kluba et al. (Prospective comparison study) compared the results of helmet therapy in 24 infants with plagiocephaly helmeted at age <6 months vs 38 helmeted at age >6 months. The degree of asymmetry was similar in both groups at the commencement of therapy, and a significant reduction in asymmetry was seen in both groups. Younger patients (<6 months) showed a greater decrease in asymmetry and attained values considered "normal." Children starting therapy later (>6 months) showed significantly less absolute improvement and did not attain values considered "normal." Duration of therapy was statistically significantly shorter in the younger patients. [30]

The guideline summarized this section by stating "Although the data were not robust enough to definitively determine the optimal time window in infancy for treatment of positional plagiocephaly with helmet therapy, it does appear that the earlier an infant is placed in a helmet, the better the treatment outcome. That being said, it must be remembered that young infants with positional plagiocephaly may see an improvement in cranial symmetry with conservative therapy or simply observation." [37]

In conclusion 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 [37]

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

RESOURCE REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CS). Medicare Coverage Database. National Coverage documents. Accessed at: http://www.cms.hhs.gov/mcd/search.asp
2. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). 501(k) Premarket Notification Database. Cranial orthosis. [use cranial orthosis for device name field]. Accessed at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

Hayes

3. Hayes Medical Technology Directory. Cranial Orthotic Devices for the Treatment of Positional Cranial Deformity. Winifred Hayes Inc. Lansdale, PA. Updated June, 2018. Archived Aug, 2019.

Peer Reviewed Publications

4. Bialocerkowski AE, Vladusic SL, Wei Ng C. Prevalence, risk factors, and natural history of positional plagiocephaly: a systematic review. Dev Med Child Neurol. 2008 Aug;50(8):577-86.
5. Cabrera-Martos I, Valenza MC, Valenza-Demet G, et al. Effects of manual therapy on treatment duration and motor development in infants with severe nonsynostotic plagiocephaly: a randomised controlled pilot study. Childs Nerv Syst. 2016 Nov;32(11):2211-2217. Epub 2016 Jul 27.

6. Couture DE, Crantford JC, Somasundaram A et al. Efficacy of passive helmet therapy for deformational plagiocephaly: report of 1050 cases. Neurosurg Focus 2013; 35(4):E4.
7. Dörhage KW, Beck-Broichsitter BE et al. Therapy effects of head orthoses in positional plagiocephaly. J Craniomaxillofac Surg. 2016 Oct;44(10):1508-1514. doi: 10.1016/j.jcms.2016.06.035. Epub 2016 Jul 7
8. Flannery AB, Looman WS, Kemper K Evidence-based care of the child with deformational plagiocephaly, part II: management. J Pediatr Health Care. 2012 Sep-Oct;26(5):320-31.
9. Freudlsperger C, Steinmacher S, Saure D, et al. Impact of severity and therapy onset on helmet therapy in positional plagiocephaly. J Craniomaxillofac Surg. 2016 Feb;44(2):110-5. doi: 10.1016/j.jcms.2015.11.016. Epub 2015 Dec 8.
10. Graham JM Jr, Gomez M, Halberg A, et al. Management of deformational plagiocephaly: repositioning versus orthotic therapy. J Pediatr. 2005a;146(2):258-262.
11. Graham JM Jr, Kreutzman J, Earl D, Halberg A, Samayoa C, Guo X. Deformational brachycephaly in supine-sleeping infants. J Pediatr. 2005b;146(2):253-257
12. Han MH, Kang JY et al. Relationship between starting age of cranial-remolding-orthosis therapy and effectiveness of treatment in children with deformational plagiocephaly. Childs Nerv Syst. 2017 May 8. doi: 10.1007/s00381-017-3427-9. [Epub ahead of print]
13. Ho JP, Mallitt KA et al. Use of external orthotic helmet therapy in positional plagiocephaly. J Clin Neurosci. 2016 Jul;29:46-51. doi: 10.1016/j.jocn.2015.12.023. Epub 2016 Mar 2.
14. Kluba S, Kraut W, Calgeer B, Reinert S, Krimmel M. Treatment of positional plagiocephaly - Helmet or no helmet? J Craniomaxillofac Surg. 2013. Epub ahead of print. October 15, 2013.
15. Laughlin J, Luerssen TG, Dias MS; and the Committee on Practice and Ambulatory Medicine, Section on Neurological Surgery. Prevention and Management of Positional Skull Deformities in Infants. Pediatrics. 2011;128(6):1236-1241
16. Lipira AB, Gordon S, Darvann TA, et al. Helmet versus active repositioning for plagiocephaly: a three-dimensional analysis. Pediatrics. 2010;126(4):e936-e945.
17. Loveday BP, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? J Craniofac Surg. 2001;12(4):308-313.
18. Mortenson P, Steinbok P, Smith D. Deformational plagiocephaly and orthotic treatment: indications and limitations. Childs Nerv Syst. 2012 Sep;28(9):1407-12
19. Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM. Analysis of posterior plagiocephaly: deformational versus synostotic. Plast Reconstr Surg. 1999;103(2):371-380.
20. Naidoo SD, Skolnick GB, Patel KB, et al. Long-term outcomes in treatment of deformational plagiocephaly and brachycephaly using helmet therapy and repositioning: a longitudinal cohort study. Childs Nerv Syst. 2015 Sep;31(9):1547-52. doi: 10.1007/s00381-015-2769-4. Epub 2015 Jun 2.
21. Paquereau J. Non-surgical management of posterior positional plagiocephaly: orthotic versus repositioning. Ann Phys Med Rehabil. 2013:56:231-49.
22. Plank LH, Giavedoni B, Lombardo JR, Geil MD, Reisner A. Comparison of infant head shape changes in deformational plagiocephaly following treatment with a cranial remolding orthosis using a noninvasive laser shape digitizer. J Craniofac Surg. 2006;17(6):1084-1091.
23. Pollack IF, Losken HW, Fasick P. Diagnosis and management of posterior plagiocephaly. Pediatrics. 1997;99(2):180-185.

24. Robinson S, Proctor M.Diagnosis and management of deformational plagiocephaly. J Neurosurg Pediatr. 2009 Apr;3(4):284-95.
25. Schweitzer T, Böhm H, Linz C, et al. Three-dimensional analysis of positional plagiocephaly before and after molding helmet therapy in comparison to normal head growth. Childs Nerv Syst. 2013;29(7):1155-1161.
26. Steinberg JP, Rawlani R, Humphries LS, Rawlani V, Vicari FA. Effectiveness of conservative therapy and helmet therapy for positional cranial deformation. Plastic and Reconstructive Surgery 2015;135(3):833-42.
27. van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, Van der Ploeg CP, Jzerman MJ, Boere-Boonekamp MM. Helmet therapy in infants with positional skull deformation: randomised controlled trial. BMJ. 2014;348:g2741.
28. Wilbrand JF, Lautenbacher N, Pons-Kühnemann J, et al. Treated Versus Untreated Positional Head Deformity. J Craniofac Surg. 2016 Jan;27(1):13-8. doi: 10.1097/SCS.0000000000002167.

2020 Literature Search regarding the role of age for helmet therapy:

29. Cevik S et al. The role of age on helmet therapy in deformational plagiocephaly and asymmetric brachycephaly. Childs Nerv Syst. 2020 Apr;36(4):803-810. doi: 10.1007/s00381-019-04354-2. Epub 2019 Sep 3. Accessed at: https://pubmed.ncbi.nlm.nih.gov/31482314/
30. Kluba S et al. What is the optimal time to start helmet therapy in positional plagiocephaly? Plast Reconstr Surg. 2011 Aug;128(2):492-8. doi: 10.1097/PRS.0b013e31821b62d6.
31. Seruya M et al. Helmet treatment of deformational plagiocephaly: the relationship between age at initiation and rate of correction. Plast Reconstr Surg. 2013 Jan;131(1):55e-61e.
32. Graham T et al.
    - A.) Significant Factors Influencing the Effectiveness of Cranial Remolding Orthoses in Infants with Deformational Plagiocephaly. J Craniofac Surg. 2019 Sep; 30(6): 1710–1713. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6786935/

    - B.) Effects of Initial Age and Severity on Cranial Remolding Orthotic Treatment for Infants with Deformational Plagiocephaly. J Clin Med. 2019 Jul 24;8(8):1097. doi: 10.3390/jcm8081097. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6786935/
33. Han MH et al. Relationship between starting age of cranial-remolding-orthosis therapy and effectiveness of treatment in children with deformational plagiocephaly. Childs Nerv Syst. 2017 Aug;33(8):1349-1356. doi: 10.1007/s00381-017-3427-9. Epub 2017 May 8.
34. Mackel C et al. The Role of Age and Initial Deformation on Final Cranial Asymmetry in Infants with Plagiocephaly Treated with Helmet Therapy. Pediatr Neurosurg. 2017;52(5):318-322. doi: 10.1159/000479326. Epub 2017 Aug 30.
35. Kunz F et al. Head Orthosis Therapy in Positional Plagiocephaly: Influence of Age and Severity of Asymmetry on Effect and Duration of Therapy. Plast Reconstr Surg. 2017 Aug;140(2):349-358.
36. Kim DJ et al. The Effects of Helmet Therapy Relative to the Size of the Anterior Fontanelle in Nonsynostotic Plagiocephaly: A Retrospective Study. J Clin Med. 2019 Nov 14;8(11):1977. doi: 10.3390/jcm8111977.

Professional Society Guidelines

37. Congress of Neurological Surgeons Guidelines. 2016: Accessed at: https://www.cns.org/
- Flannery AM, Tamber MS, Mazzola C, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guidelines for the Management of Patients With Positional Plagiocephaly: Executive Summary. Neurosurgery 2016; 79:623.
- Mazzola C, Baird LC, Bauer DF, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline for the Diagnosis of Patients With Positional Plagiocephaly: The Role of Imaging. Neurosurgery 2016; 79:E625.
- Baird LC, Klimo P Jr, Flannery AM, Bauer DF, Beier A, Durham S, Lin AY, McClung-Smith C, Mitchell L, Nikas D, Tamber MS, Tyagi R, Mazzola C. Systematic review and evidence-based guideline for the management of patients with positional plagiocephaly: the role of physical therapy. Neurosurgery. 2016 Nov;79(5):E630-1.
- Klimo P Jr, Lingo PR, Baird LC, Bauer DF, Beier A, Durham S, Lin AY, McClung-Smith C, Mitchell L, Nikas D, Tamber MS, Tyagi R, Mazzola C, Flannery AM. Systematic review and evidence-based guideline on the management of patients with positional plagiocephaly: the role of repositioning. Neurosurgery. 2016 Nov;79(5):E627-9.
- Tamber MS, Nikas D, Beier A, Baird LC, Bauer DF, Durham S, Klimo P Jr, Lin AY, Mazzola C, McClung-Smith C, Mitchell L, Tyagi R, Flannery AM. Systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. Neurosurgery. 2016 Nov;79(5):E632-3. Accessed at: https://www.cns.org/guidelines/browse-guidelines-detail/5-role-of-cranial-molding-orthosis-helmet-therapy
- Mazzola C, Baird L, Bauer D, et al. The Role of Imaging. Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on Pediatric Neurosurgery. 2016.

38. American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) and American Academy of Pediatrics (AAP). Guidelines for the Management of Patients With Positional Plagiocephaly. 2016. Accessed at: https://www.cns.org/guidelines/browse-guidelines-detail/5-role-of-cranial-molding-orthosis-helmet-therapy

Other Resources

39. UpToDate [website]: Waltham, MA: Walters Kluwer Health; 2020
- Buchanan EP, Hollier LH. Overview of craniosynostosis.
- Macias CG, Vanthaya G. Congenital muscular torticollis: Management and prognosis.

40. McKesson InterQual Criteria: CP Durable Medical Equipment.Othoses, Cranial Remodeling. 2019
41. MCG Criteria. Cranial Orthotic Devices. (A-0407). 2020.
42. Peer Review: Policy reviewed by AMR practicing physician board certified in Pediatrics, April 23, 2018 and October 8, 2020.

REVISION/REVIEW HISTORY:

Revision History:

10/11/07: New Policy

2/10/11: Policy reviewed and medical necessity criteria revised.

9/23/14: Policy reviewed and revised. Criteria changed to consider COD's investigational, experimental and unproven based on the results of a randomized controlled trial published in 2014 by van Wijk RM et al, and a Hayes rating of C for the use of cranial orthotic devices (CODs) in infants with moderate to severe positional cranial deformity who have not responded adequately to repositioning and/or physical therapy, or who are considered unlikely to respond due to age or severity of deformity. This Rating reflects uncertainty regarding the clinical benefit of CODs raised by results of the same randomized controlled trial.
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-synostocic 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 & 4/23/20: Policy reviewed, no changes to criteria.
12/9/2020: Added additional references for the role of age for helmet therapy, clarified age 3-12 months in the criteria section by adding "corrected age for premature infants".