Molina Clinical Policy
Cranial Orthotic Devices: Policy No. 041

Last Approval: 12/13/2023
Next Review Due By: December 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Craniosynostosis is a medical condition in which some or all of the sutures in the skull of an infant close prematurely. Craniosynostosis is 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 and 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 increased 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 and less pressure is placed on the infant's head during waking hours. When the deformity is moderate or severe and a trial of repositioning, 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 (DynaMed 2023; Hayes 2023; Buchanan 2021).

Cranial orthotic devices (also referred to as cranial helmets, cranial orthoses, and cranial bands) are prefabricated or custom-fitted and custom-molded devices used to redirect growth of the skull bones and reduce cranial asymmetry in infants who have positional cranial deformity. These devices 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 cranial orthotic device 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 cranial orthotic devices to obtain full symmetry throughout the course of the treatment program. Symmetrical growth is achieved by consistent evaluation and adjustments to the cranial orthotic device based on the infant'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 cranial orthotic device 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 (DynaMed 2023; Hayes 2023).

There are three 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 (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 caliper measures), a difference of > 12 mm is described as severe (DynaMed 2023). An abnormal cephalic index is identified when there are 2 standard deviations 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 sub-nasal 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 Measurements (Fish et al. 2023)

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

SD = standard deviation(s)

Regulatory Status

Cranial orthotic devices are regulated by the FDA as a class II device. FDA-approved cranial orthotic devices may be found in the FDA 510(k) database by searching product codes “MVA” or “OAN.” Cranial orthotic devices listed under product code MVA are traditional cranial orthosis modeling devices developed using manually obtained measurements of the infant’s head. Devices listed under product code OAN are developed using laser scans of the infant’s head to obtain precise measurements.

COVERAGE POLICY

Non-Synostotic Positional Plagiocephaly (or Brachycephaly) Criteria

Cranial orthotic devices **are considered medically necessary** for infants with severe non-synostotic positional plagiocephaly when **ALL** of the following criteria have been met:

1. Age for initiation of therapy is between 3-12 months (e.g., corrected age for premature infants); **AND**

2. Has failed to respond to a 2–3-month trial of alternative treatment and repositioning therapy**; **AND**

3. Documentation / anthropometric assessment to confirm moderate severe asymmetry or deformity as evidenced by **ONE** of the following criteria:
   a. Asymmetry of > 12mm in cranial vault, skull base, or orbitotragial depth (see Table 1 above)**.**
   b. Difference in diagonal diameters of cranium measures > 1.0 cm**.**
   c. Cephalic index of 90% or greater or at least ± 2 standard deviations from the mean as referenced in Table 2 above.

AND

4. Underlying neuromuscular influences have been identified, treatment has been prescribed and there are no other known neuromuscular influences; **AND**

5. Caregiver(s) can maintain a device wearing program for 23 hours a day; **AND**

6. The Member’s medical record includes the following:
   - Complete history and physical assessment, including notes describing the plagiocephaly; **AND**
   - Imaging only when clinical diagnosis is equivocal; **AND**
   - Cranial asymmetry measurements supporting the criteria above; **AND**
   - Photography of the deformity if available.

** Increase of supervised time during awake time to include prone-lying and side-lying; physical therapy (if torticollis is also present); repositioning education (including head positioning when the infant is sleeping as well as other reoccurring positions); and treating positional or congenital muscular torticollis.

Craniosynostosis Criteria

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

Limitations and Exclusions

Cranial orthotic devices **are considered not medically necessary and are non-covered** for the following:

- Devices initiated for infants < 3 months of age or >12 months of age.
- Members with untreated / non-shunted hydrocephalus and with uncorrected craniosynostosis (both are contraindications).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The use of cranial orthotic devices is controversial with conflicting evidence regarding efficacy of cranial orthotic devices in the treatment of infants and children with positional plagiocephaly. The overall quality of evidence is low and consists of studies that reported minimal or no difference between cranial orthotic device treatment and natural course observation. Additional 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. The mean age at initiation of treatment ranged from 2 months to 14 months. The mean duration of treatment ranged from 2 to 48.2 months. These studies generally reported equal or better outcomes for cranial orthotic devices 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 (Freudlsperger et al. 2016). The optimal age has not been well defined in the literature as to the role of initiating cranial orthotic devices for positional plagiocephaly. Professional society guidelines and current literature indicate that the efficacy of asymmetry reduction decreases with increasing age and the average duration of treatment increases when initiated at older ages.

van Crutchen et al. (2022) completed a 5-year follow-up study of patients included in a previous study performed by the same group to compare helmet therapy to no helmet therapy with or without physical therapy. Patients were excluded from the 5-year follow-up study if they were < 3 months or > 14 months of age at the initial visit and/or if there was a non-positional cause of cranial deformation. The follow-up for each patient that participated was completed 5-years after initial measurements were obtained. The oblique diameter difference index was used to verify the presence and assess the severity of plagiocephaly with a value higher than 106% being considered clinically relevant. The cranial proportional index was used to verify the presence and assess the severity of brachycephaly with a value higher than 95% being considered clinically relevant. Approximately 58 of the original 184 patients participated in the 5-year follow-up study. Of those 58 patients, 34 had received helmet therapy and 24 did not receive helmet therapy. Approximately 29 had plagiocephaly, 15 had brachycephaly, and 14 had a combination of plagiocephaly and brachycephaly. Results showed an overall general significant decrease in oblique diameter difference index ($p=0.031$) and cranial proportional index ($p < 0.001$). Significant decreases in the cranial proportional index were found regardless of the treatment method utilized. Significant decreases in the oblique diameter difference index were noted in the group that received a combination of helmet therapy and physical therapy ($p < 0.001$). While there were significant differences noted in the oblique diameter difference index between the helmet and no-helmet groups during the initial visit, there were no significant differences noted between either group at the 5-year follow-up visit. The difference in oblique diameter difference index was significantly higher in plagiocephaly group compared to the brachycephaly group. Researchers found that “the combination of both physical and helmet therapy may lead to a more significant decrease of positional plagiocephaly over time, whilst positional brachycephaly is not significantly affected by treatment.”

González-Santos et al. (2020) conducted a prospective cohort study to compare helmet therapy to standard pediatric physical therapy interventions (a combination of exercises and manipulative procedures aimed at motor development

and reducing cranial deformity). Inclusion criteria included normal conditions at birth (including no fetal distress), premature and low-weight infants (> 1.6 kg), with adequate Apgar scores at birth (≥ 7 at 1 minute and ≥ 8 at 5 minutes). A total of 48 infants aged 5-10 months with cranial deformities were recruited with 22 receiving helmet therapy and 26 receiving physical therapy interventions. The physical therapy cohort received two 60-minute treatment sessions per week over a 5-month period for a total of 40 sessions. Each session consisted of exercises for the neck and upper body muscles to improve motor development (10 minutes per session) followed by four manipulative techniques to reduce cranial deformity (50 minutes per session). Infants in the helmet therapy cohort received custom-made helmets that were developed using a four-dimensional scanner for "pinpoint accuracy." The helmets were worn 23 hours per day for 5 months. Regular assessments were completed by an orthotist and helmets were modified as necessary based on growth and remodeling. Each infant's cranial vault asymmetry index (CVAI) and Brunet-Lezine scale scores were calculated upon study enrollment and after 5 months of therapy. Results showed a mean age at enrollment of 6.28 ± 3.68 months in the physical therapy cohort and 5.10 ± 2.32 months in the helmet therapy cohort. The mean age at the final evaluation was 11.28 ± 5.46 months for the physical therapy cohort and 9.80 ± 4.31 months for the helmet therapy cohort. Mean CVAI at enrollment was 10.69 ± 5.58% overall, 11.59 ± 5.51% in the physical therapy cohort, and 9.62 ± 5.59% for the helmet therapy cohort. The mean CVAI at the final evaluation was 5.85 ± 3.60% for the physical therapy cohort and 4.07 ± 2.26% for the helmet therapy cohort. Brunet-Lezine scale scores at enrollment showed an overall development quotient of 80.15, 84.35 in the social area, 80.17 in the coordination area, 78.65 in the language area, and 78.03 in the motor area. Both groups showed statistically significant improvements in Brunet-Lezine scale scores from baseline with the language area showing the most improvement with 8.77. The social area had the least overall improvement with 4.08. In addition, researchers also documented birth route (forceps, cesarean, and vaginal) and gender to determine if either factor affected outcomes. No statistically significant differences were found when considering birth route and gender. Researchers found that both groups showed progressive improvement. However, there were no significant differences noted in improvement between either cohort.

Cevik et al. (2020) completed a retrospective analysis of 97 infants that received helmet therapy to determine if the age at treatment affected treatment efficacy. Infants included in the study had moderate-to-severe deformational plagiocephaly or combined deformational plagiocephaly and asymmetrical brachycephaly. Deformational plagiocephaly was defined as a CVAI > 7% and a diagonal distance > 10 mm. Asymmetrical brachycephaly was defined as a CVAI > 7% and a cephalic ratio ≥ 94. Patients were provided repositioning and physical therapy and progressed to helmet therapy if there was no improvement noted. Prior to initiating helmet therapy, cranial measurements were obtained using two different three-dimensional screening systems. Infants were divided into two groups based on age at treatment (group 1 included infants < 6 months of age and group 2 included infants > 6 months of age). A total of 89 infants were included in analysis due to treatment termination of 8 infants. Results showed better improvement in deformational plagiocephaly when helmet therapy was initiated at < 6 months of age (10.65% ± 2.8% at initiation to 4% ± 1.6% following helmet therapy) compared to > 6 months of age (8.8% ± 1.5% at initiation to 4.4% ± 2% following helmet therapy).

Graham et al. ([1-2]2019) performed a retrospective chart review to assess clinical findings about the influence of certain intake factors on treatment outcomes of cranial remolding orthoses. The study examined the statistical effect of a patient's initial deformational severity, age of initiation, presence or absence of torticollis, and presence or absence of prematurity on the outcome of a patient's cranial remolding orthoses treatment. The outcome measures of orthotic treatment being examined in this study are total cranial remolding orthoses treatment time and final head shape. A total of 2,423 charts were reviewed however only 499 met inclusion criteria and data were complete for analysis. Results indicated that longer treatment duration provided better outcomes in younger infants with or without torticollis. Due to the correlation between cranial remolding orthoses initiation age and the rate of correction, parents of older infants should be informed about treatment expectation and a longer duration of therapy may be needed. The FDA (2023) recommendation is that cranial remolding orthoses be used for infants ages 3-18 months. However, older infants with severe deformations may be unable to achieve correction due to a decreased rate of change of CVAI. Further research is needed to determine if a cut-off age should be determined as older infants may not benefit as much as a younger infant.

Han et al. (2017) investigated the optimal age for starting cranial-remolding-orthosis therapy in children with deformational plagiocephaly in a retrospective review. A retrospective review of the medical records of 310 patients diagnosed with deformational plagiocephaly was conducted. Analysis included: initial and final cranial vault asymmetry index (CVAI), age when starting therapy, duration of therapy; mean change of CVAI, improvement rate, and treatment success. Outcomes data were compared based on groups categorized on age at onset of therapy. Significant improvement was not found among patients who started therapy at age 3-5 months in terms of improvement rate and

duration of cranial-remolding-orthosis. Efficacy rates improved for patients starting therapy after 6 months of age thus the authors concluded that the optimal period to begin therapy for deformational plagiocephaly is age 5 months.

Naidoo et al. (2015) conducted a randomized controlled trial 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. The study included 84 infants (ages 5 to 6 months) with moderate to severe skull deformation, 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 randomization plan with blocks of eight. Six months of helmet therapy compared with the natural course of skull deformation were monitored. The primary outcome assessed was change in skull shape from baseline to 24 months of age using plagiocephalometry (anthropometric measurement instrument). Change scores for plagiocephaly (oblique diameter difference index) and brachycephaly (cranio-proportional 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.

Steinberg et al. (2015) performed a retrospective cohort study of 4378 infants with deformational plagiocephaly and/or deformational brachycephaly. Conservative measures alone resulted in 92% complete correction at 18 months and helmet therapy resulted in 95% complete correction. This study included 534 infants who were originally treated with conservative measures. A delay in helmet therapy in order to conduct a trial of conservative measures did not prevent complete correction, particularly in patients younger than 9 months of age and who were adherent to therapy.

National/Specialty Organizations

The Congress of Neurological Surgeons (2016) analyzed two prospective studies to explain the correlation between the age that an infant begins helmet therapy and treatment outcomes. One study was a prospective comparison study that compared results of helmet therapy in 24 infants with plagiocephaly helmeted at age <6 months vs. 38 patients that were 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) and those who started therapy <6 months showed a greater decrease in asymmetry and attained values considered normal. Duration of therapy was statistically significantly shorter in the younger patients. The other study was a prospective comparative study that assessed results of custom helmet therapy in 346 patients in seven 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. 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. Additional studies also analyzed patients who have significant cranial asymmetry that have not had previous conservative treatment. Results of the studies varied slightly but were comparable. The recommended age cut-off between infants expected to achieve a reasonable outcomes and infants expected to have a suboptimal response was slightly different between each study. The Congress of Neurological Surgeons guideline summarized that while data were not significant enough to specify an ideal range for helmet therapy for positional plagiocephaly, data does show that better treatment outcomes are found in infants with an earlier onset of treatment. In conclusion, the Congress of Neurological Surgeons guidelines recommend physical therapy and repositioning early in the process and cranial orthosis for refractory cases (Baird et al. 2016; Flannery et al. 2016; Klimo et al. 2016; Mazzola et al. 2016; Tamber et al. 2016).

A report published by Dias et al. (2020) discusses the American Academy of Pediatrics endorsement of the Congress of Neurological Surgeons 2016 guidelines. No official guidelines have been published by the American Academy of Pediatrics.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System) Codes

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
L0113	Cranial cervical orthosis, torticollis type, with or without joint, with or without soft interface material, prefabricated, includes fitting and adjustment

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/13/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review on November 29, 2023, by a practicing, board-certified physician with a specialty in Pediatrics.
04/13/2023	Revision to criteria #3a from "> 10-12mm" to ">12mm" to remove ambiguity. Coding & Billing updated with new code. Annual review scheduled for December 2023.
12/14/2022	Policy reviewed, no changes, updated references.
12/08/2021	Policy reviewed, no changes, updated references.
10/25/2022	Policy reviewed, no changes to criteria.
12/09/2020	Policy reviewed; 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". IRO Peer Review: Policy reviewed on October 8, 2020, by a practicing, board-certified physician in the area of Pediatrics.
09/18/2019	Policy reviewed, no changes to criteria.
07/10/2018	Policy reviewed; criteria changed based on new evidence-based literature and updated professional society guidelines. Updated Summary of Medical Evidence, Professional Society Guidelines and References. IRO Peer Review: Policy reviewed on April 23, 2018, by a practicing, board-certified physician in the area of Pediatrics.
09/19/2017	Policy reviewed, no changes to criteria.
09/15/2016	Policy reviewed, no changes to criteria.
12/16/2015	Policy reviewed, no changes to criteria.
9/23/2014	Policy reviewed; criteria revised to consider devices investigational, experimental, and unproven based on updated evidence-based literature (van Wiik et al. and Hayes rating of C).
02/10/2011	Policy reviewed and medical necessity criteria revised.
10/11/2007	New policy.

REFERENCES

1. Baird LC, Klimo P Jr, Flannery AM, et al. Guidelines: Congress of Neurological Surgeons 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-E631. doi: 10.1227/NEU.0000000000001429. PMID: 27759674.
2. Buchanan EP. Overview of craniosynostosis. Updated May 4, 2021. Accessed November 16, 2023. www.uptodate.com.
3. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed November 16, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
4. Çevik S, Işık S, Özkılıç A. 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. PMID: 31482314.
5. Dias MS, Samson T, Rizk EB, et al. Identifying the misshapen head: Craniosynostosis and related disorders. Pediatrics. 2020 Sep;146(3):e2020015511. doi: 10.1542/peds.2020-015511. PMID: 32868470.
6. DynaMed. Positional plagiocephaly. EBSCO Information Services. Updated May 22, 2023. Accessed November 17, 2023. www.dynamed.com.
7. Fish D, Hinton C, Barrios, A. Revisiting the cephalic index: The origin, purpose, and current applicability—A narrative review. J Prosthet Orthot. 2023 Aug;0(0):1-14. doi: 10.1097/JPO.0000000000000478.
8. 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 Nov;79(5):623-624. doi: 10.1227/NEU.0000000000001426. PMID: 27759671.

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. PMID: 26724211.
10. González-Santos J, González-Bernal JJ, De-la-Fuente et al. Infant cranial deformity: Cranial helmet therapy or physiotherapy? Int J Environ Res Public Health. 2020 Apr 10;17(7):2612. doi: 10.3390/ijerph17072612. PMID: 32290217; PMCID: PMC7177616.
11. [1]Graham T, Adams-Huet B, Gilbert N, et al. 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. PMID: 31344968; PMCID: PMC6723372.
12. [2]Graham T, Gilbert N, Witthoff K, et al. Significant factors influencing the effectiveness of cranial remolding orthoses in infants with deformational plagiocephaly. J Craniofac Surg. 2019 Sep;30(6):1710-1713. doi: 10.1097/SCS.0000000000005512. PMID: 30985500; PMCID: PMC6786935.
13. Han MH, Kang JY, Han HY, 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. PMID: 28484866.
14. Hayes. Cranial orthotic devices for the treatment of positional cranial deformity. Published May 30, 2023. Accessed November 16, 2023. https://evidence.hayesinc.com.
15. Klimo P Jr, Lingo PR, Baird LC, et al. Guidelines: Congress of Neurological Surgeons systematic review and evidence-based guideline on the management of patients with positional plagiocephaly: The role of repositioning. Neurosurgery. 2016 Nov;79(5):E627-E629. doi: 10.1227/NEU.0000000000001428. PMID: 27759673.
16. 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 Nov;79(5):E625-E626. doi: 10.1227/NEU.0000000000001427. PMID: 27776086.
17. 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. PMID: 26033379.
18. Steinberg JP, Rawlani R, Humphries LS, et al. Effectiveness of conservative therapy and helmet therapy for positional cranial deformation. Plast Reconstr Surg. 2015 Mar;135(3):833-842. doi: 10.1097/PRS.0000000000000955. PMID: 25415272.
19. Tamber MS, Nikas D, Beier A, et al. Guidelines: Congress of Neurological Surgeons 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-E633. doi: 10.1227/NEU.0000000000001430. PMID: 27759675.
20. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 501(k) premarket notification database (search product codes for “MVA” and “OAN”). Accessed November 16, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.
21. United States Food and Drug Administration (FDA) Code of Federal Regulations. Updated October 17, 2023. Accessed November 22, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5970.
22. van Cruchten C, Feijen MMW, van der Hulst RRWJ. Helmet therapy for positional cranial deformations; a 5-year follow-up study. J Craniomaxillofac Surg. 2022 Jun;50(6):499-503. doi: 10.1016/j.jcms.2022.05.001. Epub 2022 May 31. PMID: 35725060.