Molina Clinical Policy
Cranial Orthotic Devices: Policy No. 041

Last Approval: 12/8/2021
Next Review Due By: December 2022

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.[1] 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 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 and less pressure is place on the infant's head during waking hours. 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 (Hayes, 2014).

Cranial orthotic devices (CODs) (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 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 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 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 (Hayes, 2014).

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 (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 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 (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
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

COVERAGE POLICY

Non-Synostotic Positional Plagiocephaly (or Brachycephaly) Criteria

1. Cranial orthotic devices **are considered medically necessary** for infants with severe non-synostotic positional plagiocephaly when **ALL** of the following criteria have been met:
   a. Age for initiation of therapy is between 3-12 months (e.g., corrected age for premature infants); **AND**
   b. Has failed to respond to a 2-3 month trial of alternative treatment and repositioning therapy**; **AND**
   c. Documentation / anthropometric assessment to confirm moderate to ~~of~~ severe asymmetry or deformity) as evidenced by **ONE** of the following criteria:
      - Asymmetry of > 10-12mm in cranial vault, skull base or orbitotragial depth (see Table 1 above); **OR**
      - Difference in diagonal diameters of cranium measures > 1.0 cm; **OR**
      - Cephalic index of 90% or greater or at least ± 2 standard deviations from the mean as referenced in Table 2 above.

   AND
   d. Underlying neuromuscular influences have been identified, treatment has been prescribed and there are no other known neuromuscular influences; **AND**
   e. Caregiver(s) can maintain a device wearing program for 23 hours a day; **AND**
   f. 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 not considered 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 / unshunted 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 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 (Naidoo et al., 2015).

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. 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 (Freudlsperger et al., 2016). 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.

A 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. 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 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 (cranio-proportional index) were each included in an analysis of covariance, using baseline values as the covariate. (Naidoo et al., 2015).

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. (Naidoo et al., 2015).

Paquereau (2013) conducted a systematic review of 11 cohort studies and 6 literature reviews. The author concluded that orthotics are effective in correcting head deformities in patients with moderate to severe posterior positional plagiocephaly better and faster than repositioning protocols. Treatment is most efficacious when initiated before age 1. Additional research is needed on evaluation methods, treatment indications, and long-term efficacy.

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 – further, 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.

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 were analyzed. 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.

Graham et al. (2019 A) performed a retrospective chart review to assess clinical findings about the influence of certain intake factors on treatment outcomes of cranial remolding orthoses (CROs). The study examined 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. A total of 2,423 charts were reviewed however only 499 met inclusion criteria and data were complete for analysis. Results indicated that treatment outcomes in younger infants without torticollis; of patients with torticollis, longer treatment duration was successful. Due to the correlation between CRO 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 (2006) recommendation is that CROs be used for infants ages 3-18 months – 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.

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. Study participants included 98 infants who underwent helmet therapy (between 2014-2018) and had DP (cranial vault asymmetry index [CVAI] > 7% and DD > 10 mm as well as AB [CVAI > 7% and cephalic ratio (CR) ≥ 94]. Results support use of helmet therapy for DP and AB, particularly for infants with severe DP and AB as well as those with early onset of therapy (prior 6 months of age).

Age at Initiation of Helmet Therapy and Outcome

The Congress of Neurological Surgeons (CNS) (2016) analyzed two prospective studies to explain the correlation between the age that an infant begins helmet therapy and treatment outcomes (Baird, et al., 2016; Flannery et al., 2016; Klimo, et al., 2016; Mazzola et al., 2016; Tamber, et al., 2016). 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.

- Kluba et al. (2014, 2011) conducted 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.

- Seruya et al. (2013) conducted 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.

The CNS 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 CNS guidelines recommend physical therapy and repositioning early in the process and cranial orthosis for refractory cases.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes – None.

HCPCS 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

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 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

12/8/2021 Policy reviewed, no changes, updated references.
12/9/2020 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".
9/18/2019 Policy reviewed, no changes to criteria.
7/10/2018 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.
12/16/2015, 9/15/2016, 9/19/2017 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).
2/10/2011 Policy reviewed and medical necessity criteria revised.
10/11/2007 New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. https://www.cms.gov/medicare-coverage-database/search.aspx.
2. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 501(k) premarket notification database (search device name for "cranial orthosis"). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. Accessed October 29, 2021.
3. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 501(k) summary (K063395). https://www.accessdata.fda.gov/cdrh_docs/pdf6/K063395.pdf. Published December 22, 2006. Accessed October 29, 2021.

Other Evidence Based Reviews and Publications

1. AMR Peer Review: Policy reviewed on April 23, 2018 and October 8, 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Pediatrics.
2. Hayes. Cranial orthotic devices for the treatment of positional cranial deformity. https://evidence.hayesinc.com. Published July 17, 2014. Updated June 25, 2018. Archived August 17, 2019. Accessed October 29, 2021. Registration and login required.
3. MCG. Cranial orthotic devices (A-0407), 25th ed. ~~2020.~~ Updated 2021. Accessed October 29, 2021. Registration and login required.

Peer Reviewed Publications

1. 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. Accessed October 29, 2021.
2. 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. Accessed October 29, 2021.
3. Graham T, Gilbert N, Witthoff K, Gregory T, Walsh M. 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. Accessed October 29, 2021.
4. Graham T, Adams-Huet B, Gilbert N, Witthoff K, Gregory T, Walsh M. 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 October 29, 2021.
5. 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 Aug;33(8):1349-1356. doi: 10.1007/s00381-017-3427-9. Accessed Oct. 29, 2021.
6. Han MH, Young Kang J, Young Han H, Cho Y, Jang D. 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. Accessed October 29, 2021.
7. Kluba S, Kraut W, Calgeer B, Reinert S, Krimmel M. Treatment of positional plagiocephaly – helmet or no helmet? J Craniomaxillofac Surg. 2014 Jul;42(5):683-8. doi: 10.1016/j.jcms.2013.09.015. Accessed October 29, 2021.
8. Kluba S, Kraut W, Reinert S, Krimmel M. What is the optimal time to start helmet therapy in positional plagiocephaly? Plast Reconstr Surg. 2011 Aug;128(2):492-498. doi: 10.1097/PRS.0b013e31821b62d6. Accessed October 29, 2021.
9. 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. Accessed October 29, 2021.
10. Paquereau J. Non-surgical management of posterior positional plagiocephaly: Orthotic versus repositioning. Ann Phys Rehabil Med. 2013 Apr;56(3):231-49. doi: 10.1016/j.rehab.2012.12.005. Accessed October 29, 2021.
11. Seruya M, Oh AK, Taylor JH, Sauerhammer TM, Rogers GF. Helmet treatment of deformational plagiocephaly: The relationship between age at initiation and rate of correction. Plast Reconstr Surg. 2013 Jan;131(1):55e-61e. doi: 10.1097/PRS.0b013e3182729f11. Accessed October 29, 2021.
12. 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. doi: 10.1097/PRS.0000000000000955. Accessed October 29, 2021.

National and Specialty Organizations

1. Baird LC, Klimo P Jr, Flannery AM, Bauer DF, Beier A, Durham S, 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. Accessed October 29, 2021.
2. Flannery AM, Tamber MS, Mazzola C, Klimo P, Baird LC, Tyagi R, 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. Accessed October 29, 2021.
3. Klimo P Jr, Lingo PR, Baird LC, Bauer DF, Beier A, Durham S, 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. Accessed October 29, 2021.
4. 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. Accessed October 29, 2021.
5. Tamber MS, Nikas D, Beier A, Baird LC, Bauer DF, Durham S, et al. 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. Accessed October 29, 2021.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. 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. doi: 10.1111/j.1469-8749.2008.03029.x. Accessed October 29, 2021.
2. Buchanan EP. Overview of craniosynostosis. http://www.uptodate.com. Updated May 4, 2021. Accessed October 29, 2021. Registration and login required.
3. 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. doi: 10.1007/s00381-016-3200-5. Accessed October 29, 2021.
4. Couture DE, Crantford JC, Somasundaram A et al. Efficacy of passive helmet therapy for deformational plagiocephaly: Report of 1050 cases. Neurosurg Focus. 2013 Oct;35(4):E4. doi: 10.3171/2013.8.FOCUS13258. Accessed October 29, 2021.
5. 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. Accessed October 29, 2021.
6. Flannery AB, Looman WS, Kemper K. Evidence-based care of the child with deformational plagiocephaly, part II: Management. J Pediatr Health Care. Sep-Oct 2012;26(5):320-31. doi: 10.1016/j.pedhc.2011.10.002. Accessed October 29, 2021.
7. 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. Accessed October 29, 2021.
8. Kim DG, Seok Lee J, Woo Lee J, Dug Yang J, Yun Chang H, Chae Cho B, 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. Accessed October 29, 2021.

9. Kunz F, Schweitzer T, Kunz J, Wabmuth N, Stellzig-Eisenhauer A, Böhm H. 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. doi: 10.1097/PRS.0000000000003517. Accessed October 29, 2021.
10. Laughlin J, Luerssen TG, Dias MS, Committee on Practice and Ambulatory Medicine Section on Neurological Surgery. Prevention and management of positional skull deformities in infants. Pediatrics. 2011 Dec;128(6):1236-41. doi: 10.1542/peds.2011-2220. Accessed October 29, 2021.
11. Lipira AB, Gordon S, Darvann TA, et al. Helmet versus active repositioning for plagiocephaly: A three-dimensional analysis. Pediatrics. 2010 Oct;126(4):e936-45. doi: 10.1542/peds.2009-1249. Accessed October 29, 2021.
12. Loveday BP, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? J Craniofac Surg. 2001 Jul;12(4):308-13. doi: 10.1097/00001665-200107000-00003. Accessed October 29, 2021.
13. Macias CG, Gan V. Congenital muscular torticollis: Management and prognosis. http://www.uptodate.com. Updated September 25, 2019. Accessed October 29, 2021. Registration and login required.
14. Mackel C, Bonnar M, Keeny H, Lipa BM, Hwang SW. 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. Accessed October 29, 2021.
15. Mazzola C, Baird L, Bauer D, et al. Guidelines for the management of patients with positional plagiocephaly: The role of imaging. Available at Congress of Neurological Surgeons. Published 2016. Accessed October 29, 2021.
16. Mortenson P, Steinbok P, Smith D. Deformational plagiocephaly and orthotic treatment: indications and limitations. Childs Nerv Syst. 2012 Sep;28(9):1407-12. doi: 10.1007/s00381-012-1755-3. Accessed October 29, 2021.
17. Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM. Analysis of posterior plagiocephaly: Deformational versus synostotic. Plast Reconstr Surg. 1999 Feb;103(2):371-80. doi: 10.1097/00006534-199902000-00003. Accessed October 29, 2021.
18. 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 Nov;17(6):1084-91. doi: 10.1097/01.scs.0000244920.07383.85. Accessed October 29, 2021.
19. Pollack IF, Losken HW, Fasick P. Diagnosis and management of posterior plagiocephaly. Pediatrics. 1997 Feb;99(2):180-5. doi: 10.1542/peds.99.2.180. Accessed October 29, 2021.
20. Robinson S, Proctor M. Diagnosis and management of deformational plagiocephaly. J Neurosurg Pediatr. 2009 Apr;3(4):284-95. doi: 10.3171/2009.1.PEDS08330. Accessed October 29, 2021.
21. 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 Jul;29(7):1155-61. doi: 10.1007/s00381-013-2030-y. Accessed October 29, 2021.
22. Tamber MS, Nikas D, Beier A, Baird LC, Bauer DF, Durham S, et al. Guidelines for the management of patients with positional plagiocephaly: The role of cranial modeling orthosis (helmet) therapy. Published 2016. Available at the Congress of Neurological Surgeons (CNS). Accessed October 29, 2021.
23. 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 May 1;348:g2741. doi: 10.1136/bmj.g2741. Accessed October 29, 2021.
24. 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. Accessed October 29, 2021.

APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*