Molina Clinical Policy
Cranial Orthotic Devices
Policy No. 041

Last Approval: 10/14/2026
Next Review Due By: October 2027

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OVERVIEW

Craniosynostosis is a medical condition in which one or more 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,** without synostosis, 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 (Buchanan 2025).

There are three types of positional cranial deformity: positional plagiocephaly (characterized by an abnormal cranial vault asymmetry index), positional brachycephaly (defined by an abnormal cranial index), and combined positional plagiocephaly and brachycephaly (abnormal cranial vault asymmetry index and cranial index). Plagiocephaly is diagnosed via a variety of criteria, such as a $\geq$ 12mm difference in cranial asymmetry measurements, $\geq$ 8.75% on the Children's Healthcare of Atlanta Plagiocephaly Severity Scale (also referred to as the Cranial Vault Asymmetry Index), or an abnormal cephalic index of 2 standard deviations above or below the mean measurements (Holowka et al. 2016; Jung & Yun 2020; Miyabayashi et al. 2023). While these tools help diagnose plagiocephaly, the literature is inconclusive for a standardized definition of severity. Positional plagiocephaly is treated conservatively and often spontaneously resolves 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, conservative measures such as repositioning, stretching, and/or physical therapy are implemented. If these measures fail, a pediatric specialist in craniofacial deformities may prescribe a cranial remodeling helmet to improve cranial symmetry (Hayes 2025; Buchanan 2025).

Cranial orthotic devices (also referred to as cranial helmets, cranial orthoses, and cranial bands) are prefabricated or custom-made 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. Discontinuation of treatment occurs when a desirable degree of symmetry or improvement is obtained (Hayes 2025).

Regulatory Status

Cranial orthotic devices are regulated by the FDA as a class II device. FDA-cleared 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 typically developed using manual or scanned 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.

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COVERAGE POLICY

Non-Synostotic Positional Plagiocephaly (or Brachycephaly) Criteria
Cranial orthotic devices may be **considered medically necessary** for infants with severe non-synostotic positional plagiocephaly when ALL the following criteria have been met:

1. Documentation in the member's medical record of ALL the following:
   a. Complete history and physical assessment from the primary care provider confirming diagnosis of non-synostotic positional plagiocephaly, and must include information describing the plagiocephaly and status of gross motor development
   b. Cranial asymmetry measurements supporting criteria 4 below
   c. Imaging, only when clinical diagnosis is equivocal
   d. Photography of the deformity, if available
   e. Physical therapy (PT) notes when PT is indicated

2. Age for initiation of therapy is between 3-12 months (corrected age for premature infants)

3. Documented failure (e.g., serial measurements) to respond to at least 2-months of alternative treatment, which includes ALL the following:
   a. Repositioning education (e.g., alternating head positioning during sleeping and other reoccurring positions)
   b. Increasing supervised awake time positioned prone-lying and side-lying
   c. Physical therapy, if torticollis is also present
   d. Treating positional or congenital muscular torticollis, if present

4. Confirmed moderate to severe cranial asymmetry as evidenced by ONE of the following criteria:
   a. Asymmetry of ≥ 12mm (1.2cm) in cranial vault, skull base, or orbitotragial depth measurements (see Table 1 in Supplemental Information section)
   b. Cephalic index of 90% or greater OR at least ± 2 standard deviations from the mean (see Table 2 in Supplemental Information section)
   c. Cranial Vault Asymmetry Index (CVAI) ≥ 8.75% (see Table 3 in Supplemental Information section)

5. Any underlying neuromuscular influences have been identified, treatment has been prescribed, and there are no other known neuromuscular influences

6. Caregiver(s) can maintain a device wearing program for 23 hours a day

Craniosynostosis Criteria
Cranial orthotic devices for the postoperative treatment of craniosynostosis may be **considered medically necessary** for infants with synostotic plagiocephaly to correct continued asymmetry following surgery

Second Cranial Orthotic Device
A second cranial orthotic device may be **considered medically necessary** when ONE or more of the following criteria are met:

1. The infant continues to exhibit clinically significant, as stipulated in criteria 4 above, cranial asymmetry following completion of initial orthotic therapy and there is a reasonable expectation of meaningful improvement in head shape with ongoing orthotic intervention

2. The infant has outgrown the initial orthosis. Documentation that the original orthosis cannot be modified to accommodate infant's head, necessitating a new device to accommodate cranial growth is required

3. The infant is 8 months of age or younger and has not yet developed midline head control, rolling, or sitting, indicating ongoing vulnerability to positional forces

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Limitations and Exclusions

Cranial orthotic devices are considered **contraindicated** in ALL the following, and thus not medically necessary:

1. Devices initiated for infants < 3 months of age or > 12 months of age

2. Members with untreated / non-shunted hydrocephalus, uncorrected craniosynostosis, or other conditions such as calcified cephalohematoma

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 remains controversial, with conflicting evidence regarding their efficacy in the treatment of infants with positional plagiocephaly. Current evidence consists primarily of nonrandomized controlled studies, prospective and retrospective cohort studies, case series, observational studies, and systematic reviews, while conclusions are limited by heterogeneity in patient selection, outcome measurements, treatment protocols, and severity definitions. Some studies have reported little or no difference between cranial orthotic therapy and conservative treatment or the natural course of plagiocephaly, while some studies have shown faster or greater improvement in cranial symmetry with orthotic therapy, particularly with early treatment initiation and among infants with moderate-to-severe deformity. Conservative therapy, including repositioning and physical therapy, remains the first line treatment for mild to moderate deformity. Cranial orthotic therapy is reserved for severe or persistent deformity that has failed to respond to conservative treatment. The optimal age of initiating orthotic treatment has not been well defined, though professional society guidelines and current literature indicate that earlier treatment is associated with greater rates of correction and shorter treatment duration. Overall, the literature suggests that cranial orthotic therapy may accelerate correction, although differences between its effects and the effects of conservative management may diminish over time.

Systematic Reviews and Meta-Analysis

Castaño-Bustos et al. (2026) conducted a systematic review to evaluate the efficacy of conservative management versus cranial orthotic therapy for non-synostotic positional plagiocephaly in infants. The review included 4 observational cohort studies, with two being prospective and two retrospective, for a total of 1,183 patients. Treatment began between 2 and 7 months of age, and included repositioning, physical therapy, helmet therapy, or combinations of these interventions. Across the studies, helmet therapy was associated with faster improvement and generally greater early improvement in cranial shape, particularly among infants with moderate to severe deformity. In the largest study (n = 991), helmet therapy produced a mean decrease in the Cranial Index (CI) of -4.5 (from 97.7 to 93.2) compared to -2.0 (from 95.7 to 93.8) with repositioning therapy. In a smaller study (n = 34), helmet therapy produced a mean decrease in the Cranial Vault Asymmetry Index (CVAI) of -4.50% (from 8.10% to 3.66%) compared to -3.59% (from 7.26% to 3.67%). In another study (n = 100), helmet therapy reduced CVAI by -6.65% (from 10.81% to 4.16%) compared with conservative therapy at -3.32% (from 8.3% to 5.05%). Earlier treatment, particularly before 5-6 months of age, was associated with greater and more rapid improvement. Greater baseline severity was associated with larger absolute reductions in asymmetry but lower likelihoods of complete normalization. Additionally, torticollis and poorer treatment adherence were associated with less favorable outcomes. In studies with extended follow-up beyond 12 to 24 months, differences in final CVAI and CI values between conservative treatment and orthotic therapy groups tended to diminish, particularly among infants with mild-to-moderate deformity. Adverse effects of helmet therapy were mild and generally resolved with helmet adjustment, skin care, or brief treatment interruptions. Limitations include a small number of eligible studies, differences in baseline severity definitions, observational design, treatment timing and duration, follow-up intervals, outcome measures, and the difficulty separating treatment effects from spontaneous cranial remodeling. The authors concluded that repositioning and physical therapy are effective and appropriate first-line treatments, particularly for mild deformity, while cranial orthotic therapy appears to provide faster early correction in moderate-to-severe cases or when conservative treatment is unsuccessful. However, because long-term differences tend to diminish, helmet therapy may accelerate correction rather than alter final long-term cranial morphology.

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Hashemi et al. (2024) conducted a systematic review to evaluate the clinical factors associated with the success and duration of cranial remolding orthosis treatment for non-syndromic, non-synostotic skull deformities, particularly plagiocephaly and brachycephaly. The review included 25 studies, which included 7 prospective or 18 retrospective cohort studies, for a total of 7,594 patients. Orthosis initiation ranged from 19 days to 21.6 months, and treatment duration ranged from 6.3 to 39.7 weeks. A meta-analysis could not be performed due to substantial heterogeneity. Of studies that examined age and treatment success, 18 out of 21 reported that increasing age at therapy initiation was associated with less successful correction. Of studies that examined age and treatment duration, 11 of 12 reported that older age was associated with long treatment, and the authors found that children younger than 8 months generally required shorter treatment. One study estimated that treatment duration increased by 0.391 months for every additional month at age of orthosis initiation. In studies that examined severity, 10 of 12 studies found that a greater severity was associated with a lower likelihood of achieving desired outcomes and 6 of 6 studies found that a greater initial severity was associated with longer treatment. The authors concluded that moderate evidence supports age at orthosis initiation and deformity severity as predictors of treatment duration, and that age, compliance, and deformity severity as predictors of treatment success. Torticollis and gestational age do not appear to reduce the likelihood of treatment success.

Blanco-Diaz et al. (2023) completed a systematic review to assess the effectiveness of conservative treatments, including repositioning techniques, physical therapy, and orthotic devices, for positional plagiocephaly in infants. The review encompassed 5,051 patients across nine studies, including 5 RCTs and 4 clinical trials. Outcomes included objective cranial measurement tools such as the CI, CVAI, Oblique Diameter Difference Index (ODDI), and others. The evidence for helmet therapy was mixed. For example, in an RCT (n= 84) of infants aged 5-6 months with moderate to severe deformation, helmet therapy was no more effective than the natural progression of plagiocephaly, as measured by ODDI (mean difference of -0.2, 95% CI -1.6 to 1.2, p = 0.80), or brachycephaly, as measured by the cranio-proportional index (mean difference of 0.2, 95% CI -1.7 to 2.2, p = 0.81). In the largest clinical trial (n = 4378), 77.1% of patients assigned to conservative treatment (repositioning with or without physical therapy) achieved complete correction, while 15.8% were transitioned to helmet therapy after 4.1 $\pm$ 1.4 months and 7.1% ultimately had incomplete correction. Of all the patients treated with helmet therapy, 95% achieved complete correction, and there were no differences in outcomes between crossover patients and those who received helmet therapy as first-line treatment (94.4% vs 96.1%, p = 0.375), indicating that in most patients, delaying helmet therapy for a trial of conservative treatment does not prevent complete correction. Risk factors for failure included poor compliance, advanced age, developmental delay, prolonged torticollis, and the severity of initial cranial ratio and diagonal difference. The review emphasizes that physical therapy, particularly manual therapy combined with counseling for parents or caregivers, remains the first-line intervention for non-synostotic asymmetries, with helmet therapy considered a second-line option for moderate to severe cases that present at a later stage or that persist despite physical therapy and repositioning therapy. Although some literature questions the cost-effectiveness and commercial influences of helmet therapy, the clinical benefit for severe cases is well-supported. While cranial growth slows after 12 months of age, improvement remains possible in select cases, and residual asymmetries may continue to self-correct post-treatment. The evidence base is limited by heterogeneity in study designs, small sample sizes, and variability in outcome measures, but current guidelines recommend helmet therapy for infants presenting with persistent or late-stage moderate to severe PP.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Chhatwani et al. (2026) conducted a retrospective cohort study to compare the outcomes of cranial orthotic treatment versus physiotherapeutic-osteopathic treatment (POT) in infants with positional plagiocephaly. The study included 123 patients, with 95 receiving helmet therapy + POT and 28 receiving POT alone. Mean age at treatment initiation was 5.4 $\pm$ 1.1 months in the helmet group and 5.1 $\pm$ 1.0 in the control group. Patients with craniosynostosis and those older than 8 months were excluded. All helmets were individually manufactured and worn for approximately 23 hours a day, with adjustments every 4-6 weeks. Mean treatment duration was 2.2 $\pm$ 0.6 months with helmet therapy versus 1.6 $\pm$ 0.5 months for POT alone ($p < 0.001$). Clinical improvement was assessed using pre and post treatment 3D photo-optical head scans, and measurements primarily using the CI and 30-degree diagonal difference (DD). In the helmet group, mean CI decreased from 91.3% to 87.8% for a mean correction of 3.6 $\pm$ 3.6 points ($p < 0.001$) versus 90.5% to 90.4% in the control group, for a mean correction of 0.1 $\pm$ 2.1 ($p = 0.923$). Mean DD decreased from 14.4 to 9.6 mm with helmet therapy for a correction of 4.8 $\pm$ 2.8 mm ($p < 0.001$) compared with 13.0 to 12.6 mm for the control group, for a mean correction of 0.4 $\pm$ 2.3 mm ($p = 0.719$). Severe cases showed the largest DD correction with helmet therapy (6.9 $\pm$ 2.4 mm, $p < 0.001$) and earlier helmet initiation was associated with greater DD improvement ($p = 0.035$) with the greatest corrections observed when treatment began before 4 months of age. Males showed greater CI reduction than females (4.2 $\pm$ 3.6% vs 2.5 $\pm$ 3.3%, $p = 0.045$), although sex did not significantly affect DD correction ($p = 0.540$).

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Study limitations include retrospective and nonrandomized design, the use of a convenience sample without a prospective sample-size calculation, substantially unequal group sizes, and a shorter treatment period in the control group. Additionally, treatment assignment was related to deformity severity rather than randomized, and treatment cessation in the helmet group was based on parental choice rather than standardized metric thresholds. The authors concluded that cranial orthotic therapy combined with POT appeared more effective than POT alone and produced significantly greater reductions in both CI and DD. Standardized diagnostic and outcome measurement methods are needed in future research.

Vogt et al. (2025) conducted a single-center, retrospective cohort study to compare the effects of helmet therapy with conservative management for positional plagiocephaly in infants. The study included 72 patients treated for at least level 2 positional plagiocephaly, with treatment lasting for at least 90 days. Thirty-six patients received helmet therapy after an initial 6-week period of conservative treatment, while 36 patients continued conservative management with physiotherapy and repositioning. The primary outcome was monthly CVAI correction speed. Secondary outcomes included absolute CVAI reduction and reductions in plagiocephaly severity level. Helmet therapy showed a mean severity level reduction of 0.89 $\pm$ 0.73 compared to 0.39 $\pm$ 0.66 with continued conservative management ($p = 0.007$). However, patients beginning helmet therapy were significantly older than those continuing conservative treatment (31.9 weeks $\pm$ 6.6 vs. 21.0 $\pm$ 5.7 weeks, $p < 0.001$). Monthly CVAI correction speed was comparable between groups at 0.66 $\pm$ 2.09 vs. 0.64 $\pm$ 0.55 but was not statistically significant ($p = 0.964$). Reductions in severity levels were achieved in 67% of helmet therapy patients versus 42% of conservative management patients, which approached but did not achieve statistical significance wither ($p = 0.058$). The authors concluded that both conservative management and helmet therapy reduced cranial asymmetry with no significant difference in correction speed. Early treatment initiation was the strongest predictor of improvement and longer treatment durations were associated with better outcomes. A trend toward a greater reduction in severity level was observed with helmet therapy which suggests potential benefit in more severe cases.

Kajita et al. (2024) completed a retrospective, single-arm study to evaluate the efficacy of cranial orthosis therapy for non-synostotic deformational plagiocephaly using both two-dimensional (2D) and three-dimensional (3D) assessment modalities. A total of 1,038 infants were treated with a custom-fabricated cranial orthosis (Aimet), with treatment initiated at a mean age of approximately 4.6 months. The study employed 2D metrics, cranial asymmetry (CA), and CVAI, as well as 3D metrics, anterior symmetry ratio (ASR) and posterior symmetry ratio (PSR), to quantify cranial shape abnormalities and therapeutic outcomes. CA, CVAI, ASR, and posterior symmetry PSR were used to quantify head shape abnormalities. Prior to helmet therapy, the mean CA was 15.1 mm, mean CVAI was 10.3%, ASR averaged 90.7%, and PSR was 80.6%. Following intervention, all four metrics demonstrated statistically significant improvement ($p < 0.001$, paired t-test), underscoring the effectiveness of cranial orthotic therapy in reducing asymmetry. There was greater normalization of cranial symmetry ratios in patients who initiated treatment at a younger age and in those presenting with more severe baseline deformities. The findings highlight the clinical utility of early helmet therapy in achieving cranial remodeling and highlight the superiority of 3D evaluation techniques in capturing volumetric changes not fully represented by traditional 2D measurements. The study supports the integration of multimodal assessment strategies in the management of positional plagiocephaly and reinforces the importance of timely intervention to optimize therapeutic outcomes.

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

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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."

National and Specialty Organizations

The **Royal Children's Hospital Melbourne** (2024) published a clinical practice guideline on positional plagiocephaly. The Paediatric Improvement Collaborative has endorsed this guideline. Helmet therapy may offer benefits for infants with severe positional cranial deformities that do not respond adequately to repositioning strategies or physiotherapy. While the intervention facilitates cranial remodeling, some residual skull asymmetry typically remains post-treatment. The optimal window for initiating helmet therapy is approximately 6 to 7 months of age, although children with developmental delays or torticollis may be considered with less pronounced deformity, given their reduced likelihood of spontaneous correction. After 10 months of age, helmet therapy becomes less effective due to diminished cranial growth and closure of the anterior fontanelle. The mechanism involves relieving pressure from flattened skull regions (as in plagiocephaly) or guiding occipital growth to prevent further widening in brachycephaly, without reversing prior changes. Helmets are custom fitted by an orthotist and are typically worn for 23 hours per day over a period ranging from 6 weeks to 3 months, depending on individual response and head shape improvement.

The **Congress of Neurological Surgeons (CNS), American Association of Neurological Surgeons (AANS), American Academy of Pediatrics (AAP)** published guidelines for the management of patients with positional plagiocephaly (Tamber et al. 2016). The authors 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 reasonable outcomes and infants expected to have a suboptimal response was slightly different between each study. The authors summarized that while data was 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. The guidelines recommend helmet therapy for infants with persistent moderate to severe plagiocephaly after a course of conservative treatment (repositioning and/or physical therapy) or when presenting at an advanced age. These are Level II recommendations based on "uncertain clinical certainty" (Tamber et al. 2016).

The **AAP** published a clinical report on the identification and management of craniosynostosis and related disorders, which was published in 2020 and reaffirmed in 2025 (Dias et al. 2020). The AAP states that early positional changes are sufficient for most infants, while physical therapy is recommended when torticollis is present. For infants with moderate or severe deformities that have not responded to conservative treatment, referral at approximately 5 to 6 months of age may be considered to discuss cranial molding helmet therapy. The AAP emphasizes that while the use of a molding helmet may be considered for moderate or severe deformity, it is not required. For craniosynostosis treated with endoscopic suturectomy, surgery should be performed early, during the first few months of life, and followed by up to 12 months of postoperative molding helmet therapy for 23 hours a day to achieve correction comparable to open techniques. For open cranial vault reconstruction, postoperative helmeting is not routinely used.

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SUPPLEMENTAL INFORMATION

TABLE 1 Cranial Asymmetry Measurements

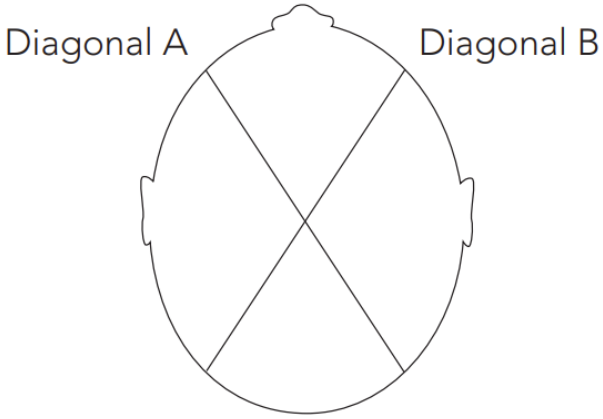
Anthropometric Data	Measurement	Measures
Skull base	Subnasal point to left tragus *minus* subnasal point to right tragus	Right and left morphological face height and maxillary depth
Cranial Vault	Left frontozygomatic point to right euryon *minus* right frontozygomatic point to left euryon	Cranial vault asymmetry
Orbitotragial Depth	Left exocanthion point to left tragus *minus* right exocanthion point to right 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)

TABLE 3 Cranial Vault Asymmetry Index (CVAI)



$$CVAI = \frac{|A-B| \times 100}{A \text{ or } B \text{ (whichever is greater)}}$$

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
S1040	Cranial remolding orthotic, 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

10/14/2026	Policy revised. Added requirement of primary care notes with gross motor development details, and physical therapy notes.
10/08/2025	Policy revised. Added criteria for a second cranial orthotic and CVAI measurements. Removed "Difference in diagonal diameters of cranium measures > 10mm (1cm)". Updated Summary of Medical Evidence and References. IRO Peer Review on September 12, 2025, by a practicing physician, board certified in Pediatrics.
10/09/2024	Policy reviewed, no changes to coverage criteria
12/13/2023	Policy reviewed, no changes to coverage criteria. IRO Peer Review on November 29, 2023, by a practicing, board-certified physician with a specialty in Pediatrics.
04/13/2023	Policy revised. Revised 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 to coverage criteria
12/08/2021	Policy reviewed, no changes to coverage criteria
10/25/2022	Policy reviewed, no changes to coverage criteria.
12/09/2020	Policy revised; 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 Pediatrics.
09/18/2019	Policy reviewed, no changes to coverage 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 Pediatrics.
09/19/2017	Policy reviewed, no changes to coverage criteria.
09/15/2016	Policy reviewed, no changes to coverage criteria.
12/16/2015	Policy reviewed, no changes to coverage criteria.
09/23/2014	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.

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