Plagiocephaly and Craniosynostosis Treatment

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Instructions for Use

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Related Commercial Policies

- Cosmetic and Reconstructive Procedures
- Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements

Community Plan Policy

- Plagiocephaly and Craniosynostosis Treatment

Coverage Rationale

Cranial Orthotic Devices are proven and medically necessary for treating infants with the following conditions:

- Craniofacial asymmetry with Severe (non-synostotic) Positional Plagiocephaly when all of the following criteria are met:
  - Infant is between 3-18 months of age
  - Severe Plagiocephaly is present with or without torticollis
  - Documentation of a trial of conservative therapy of at least 2 months duration with cranial repositioning, with or without stretching therapy
- Craniosynostosis (i.e., synostotic Plagiocephaly) following surgical correction

Cranial Orthotic Devices used for treating infants with mild to moderate Plagiocephaly do not improve physiologic function and are considered cosmetic.

Note: Refer to the Description of Services section for additional information regarding Anthropometric Measurements and Cephalic Index. Refer to the Related Policies for detailed information related to repair and replacement of Cranial Orthotic Devices.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT/HCPCS Codes*	Required Clinical Information
Surgical Treatment	

21175	Medical notes documenting the following:
	• History of medical conditions requiring treatment or surgical invention which includes all of the following:
	  ○ To prove medical necessity, a well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment
	  ○ Recurrent or persistent functional impairment caused by the abnormality
	• Clinical studies/tests addressing the physical/physiologic abnormality confirming its presence and degree to which it causes impairment
	• Physician plan of care with proposed procedures and whether this request is part of a staged procedure; indicate how the procedure will improve and/or restore function

Cranial Orthosis	

L0112
S1040
	Provide the following:
	• Current prescription from physician
	• Reason for the orthotic
	• Diagnosis
	• Physical exam related to support the need of the orthotic; include the neurological, circulatory, skin and musculoskeletal examination that supports the request
	• Orthotist notes to include the following:
	  ○ Equipment quote with billing codes and cost
	  ○ Reason for the orthotic
	  ○ Cephalic index
	  ○ Anthropometric Measurements
	• Date and type of injury/ surgery, if applicable
	
	For a replacement request, provide medical notes documenting:
	• Age of current orthotic
	• Reason for replacement

**For code descriptions, see the Applicable Codes section.*

Definitions

Cranial Orthotic Devices (CODs): Prefabricated or custom-fitted and custom-molded devices that allow for growth in certain regions of the cranium and restrict growth in others. CODs do not alter the magnitude of intrinsic brain growth but rather its direction. Designs may be active or passive in nature, rigid or flexible, or hinged or circumferential. Symmetrical growth is achieved by consistent evaluation and adjustments to the COD based on the child's head shape and growth patterns (Hayes, 2018).

Craniosynostosis: Premature closure of one or more sutures of the skull (Tabers Cyclopedic Medical Dictionary, 2017). Craniosynostosis is a non-positional cause of abnormal head shape in infants and occurs when one or more of the sutures in the infant's skull fuse prematurely. The premature fusion of one or more sutures puts pressure on the brain, potentially restricting brain growth and exerting pressure on the other skull bones to expand out of proportion, leading to abnormal skull shape. This can result in neurologic damage and progressive craniofacial distortion.

The involved suture and anatomical name is listed below for the types of Craniosynostosis:

- Primary Craniosynostosis (PC) is a general term for the improper development and premature closure of sutures of the bones of the skull.
- Simple (or isolated) Craniosynostosis classifications include:
  - Sagittal or scaphocephaly (cephal="head") – scaphocephaly (boat-shaped) – dolichocephaly (long)
  - Coronal (bilateral) – brachycephaly (short)

- Coronal (unilateral) – Plagiocephaly (diagonal)
- Coronal (anterior Plagiocephaly)
- Metopic trigonocephaly (triangle-shaped)
- Lambdoidal (bilateral) – posterior or occipital brachycephaly
- Lambdoidal (unilateral) – posterior or occipital Plagiocephaly

- Compound Craniosynostosis

Plagiocephaly: Flattening of one side of the skull producing an asymmetrically shaped head (Tabers Cyclopedic Medical Dictionary, 2017). Plagiocephaly is most often the result of an infant spending extended periods of time on their back, typically during sleep. Plagiocephaly can also occur as a feature of other disorders (e.g., craniofacial disorders, torticollis, and cervical anomalies) and is categorized as either positional or non-positional (premature union of cranial sutures).

Positional Plagiocephaly: An acquired flattening of the skull of an infant, usually after repeatedly sleeping in a single position (e.g., on the infant's back, to prevent Sudden Infant Death Syndrome (SIDS)). Also referred to as deformational Plagiocephaly, it can usually be treated nonoperatively by repositioning the developing infant frequently, or by having the child wear a protective, adjustable helmet while resting (Tabers Cyclopedic Medical Dictionary, 2017).

Severe Plagiocephaly: An asymmetry of 10 mm or more in one of the following Anthropometric Measurements: cranial vault, skull base, or orbitotragial depth; or a Cephalic Index of at least 2 standard deviations above or below the mean for the appropriate gender/age.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)

CPT® is a registered trademark of the American Medical Association

CDT Code	Description
D5924	Cranial prosthesis

CDT® is a registered trademark of the American Dental Association

HCPCS Code	Description
L0112	Cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
L0113	Cranial cervical orthotic, torticollis type, with or without joint, with or without soft interface material, prefabricated, includes fitting and adjustment
S1040	Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

Description of Services

Cranial asymmetry can be classified as non-synostotic (or deformational) caused by positioning, or synostotic caused by abnormal suture development. Synostotic plagiocephaly usually requires surgical correction (Peitsch et al., 2002).

Non-Synostotic Positional Plagiocephaly

Positional Plagiocephaly is treated conservatively and many cases does not require any specific treatment as the condition may resolve spontaneously when the infant begins to roll over and, later, to sit up. When the deformity is moderate or severe and a trial of repositioning the infant has failed, a specialist in craniofacial deformities may prescribe a COD to remodel the misshapen head.

Treatment for Positional Plagiocephaly

Treatment for Positional Plagiocephaly is based on the age of the infant and the severity of the deformity. The optimal treatment is prevention through active counterpositioning of sleeping babies until they are able to move their heads freely during sleep, usually by six months of age.

While no accurate estimates of the incidence of Positional Plagiocephaly are currently available, the supine sleeping position, currently recommended by the American Academy of Pediatrics (AAP) to reduce the risk of SIDS, has been associated with an increased frequency of Positional Plagiocephaly due to pressure of the back of the head against a firm mattress. Prevention and management of positional skull deformities in infants includes anticipatory counseling for parents, mechanical adjustments, and exercises (Laughlin et al., 2011).

Plagiocephaly with Synostosis

Craniosynostosis is characterized by the premature closure of one or more of the fibrous joints between the bones of the skull (called the cranial sutures) before brain growth is complete. Closure of a single suture is most common. In contrast to normal skull growth, in which the skull expands uniformly to accommodate the growth of the brain, premature closure of a single suture restricts the growth in that part of the skull and promotes growth in other parts of the skull where sutures remain open. This results in an abnormal shape of the skull, but does not prevent the brain from expanding to a normal volume. However, when more than one suture closes prematurely, the skull cannot expand to accommodate the growing brain, which leads to increased pressure within the skull and impaired development of the brain (National Institute of Neurological Disorders and Stroke (NINDS), 2017).

Craniosynostosis requires surgical treatment to open the prematurely closed suture(s) in order to allow for normal brain growth (NINDS, 2017; Clayman et al., 2007). The major complications associated with uncorrected Craniosynostosis include increased intracranial pressure and abnormal brain development.

Surgical treatment of Craniosynostosis has evolved from simple excision of the stenosed suture to complex procedures such as cranial vault remodeling and fronto-orbital advancement. Cranial vault remodeling involves removal of the fused suture, multiple osteotomies and remodeling of the skull using plates and screws as necessary. These operations are usually recommended for infants aged 6 to 8 months, are lengthy (4-8 hours), and associated with significant blood loss (300-1500mL), need for blood transfusions and can require hospitalization for 4-7 days (Clayman et al, 2007).

Spring-mediated cranioplasty is a minimally invasive alternative to the standard surgical procedure for Craniosynostosis. Two dynamic springs made of steel are fashioned in the operating room by the surgeon and placed in the gap left by the removal of the fused suture. The child has a second, smaller operation to remove the 2 springs approximately 3-4 months after the initial procedure (Lauritzen et al., 1998).

Endoscopic strip craniectomy is another recently developed, less invasive surgery to treat Craniosynostosis. The principal goal of this procedure is to remove stenosed sutures, and to allow the skull to expand into a normal shape as the brain grows. After surgery, the infant wears a customized helmet for 11 to 12 months to guide and constrain this expansion and correction process. The procedure is best performed when the infant is < 6 months old (Jimenez et al., 2000).

CODs have also been used after traditional surgery for Craniosynostosis. The devices are used to protect the remodeled skull, prevent recurrence of the deformity, and promote corrective reshaping. In this case, they are used to maintain the remodeling accomplished by surgery, rather than to reshape the skull.

A standard method of measurement for Plagiocephaly and Craniosynostosis has not been adopted. Methods include the use of clinical observation and precision calipers. Other methods include the use of elastic and low temperature thermoplastic bands

wrapped circumferentially around the widest point of the head which may then be digitized by photography, photocopied, or scanned to allow measurement and head shape to be analyzed (McGarry et al., 2008).

Evaluation of Plagiocephaly

The diagnosis of the type of craniosynostosis is confirmed through physical examination and imaging studies.

Anthropometric data, or the measurements used to evaluate abnormal head shape by measuring the distance in millimeters from one pre-designated point on the face or skull to another, must document moderate to severe plagiocephaly.

The evaluation of cranial asymmetry may be based on 1 or more of 4 anthropometric measures: cranial vault, skull base, orbitotragial depth measurements or the cephalic index.

Specifications for Taking Anthropometric Measurements	
Anthropometric Measure	Measurement
Cranial Vault	[left frontozygomatic point (fz) to right euryon (eu)] minus [right frontozygomatic point (fz) to left euryon (eu)]
Skull Base	[subnasal point (sn) to left tragus (t)] minus [subnasal point (sn) to right tragus (t)]
Orbitotragial Depth	[left exocanthion point (ex) to left tragus (t)] minus [right exocanthion point (ex) to right tragus (t)

Evaluation of cranial asymmetry may also be based on the Cephalic Index, a ratio between the width and length of the head. Typically, head width is calculated by subtracting the distance from euryon (eu) on one side of the head to euryon on the other side of head and multiplying by 100. Head length is generally calculated by measuring the distance from glabella point (g) to opisthocranion point (op). The Cephalic Index is then calculated as head width
(eu – eu) x 100 divided by head length (g – op).

Cephalic Index (AAOP, 2004)						
Gender	Age	- 2 SD	- 1SD	Mean	+ 1SD	+ 2SD
Male	16 days – 6 months	63.7	68.7	73.7	78.7	83.7
	6 – 12 Months	64.8	68.7	78.0	84.6	91.2
	13 – 18 Months	Apply the 12-month measurements for children 13-18 months of age				
Female	16 days – 6 Months	63.9	68.6	73.3	78.0	82.7
	6 – 12 Months	69.5	74.0	78.5	83.0	87.5
	13 – 18 Months	Apply the 12-month measurements for children 13-18 months of age				

The Cephalic Index is considered abnormal if it is 2 standard deviations above or below the mean measurements (Farkas and Munro, 1987).

Patient Selection Criteria

There are no definable standard criteria for starting helmet therapy. Treatment decision is influenced more strongly by factors other than medical evidence, such as physician preference (Kim et al., 2013).

Clinical Evidence

Cranial Orthotic Devices (CODs)

CODs are used in infants for the treatment of positional plagiocephaly, deformation of the head that results from external pressure applied to the soft infant skull.

Lam et al. (2017) performed an observational study with a retrospective chart review of their single institutional experience (2008-2014) analyzing improvements associated with various treatment modalities for positional plagiocephaly. Univariate and

multivariate analyses were used to assess the impact of these variables on the change in measured oblique diagonal difference (ODD) on head shape surface scanning pre- and posttreatment. A total of 991 infants < 1 year of age (average age 6.2 months) were evaluated for cranial positional deformity in a dedicated clinical program. The most common deformity was occipital plagiocephaly (69.5%), followed by occipital brachycephaly (18.4%) or a combination of both (12.1%). Recommended treatment included repositioning (RP), physical therapy (PT) if indicated, or the use of a customized cranial orthosis (CO). Of the 991 eligible patients, 884 returned for at least 1 follow-up appointment and 552 patients were followed to treatment completion. Of the 991 patients, 543 (54.8%) had RP or PT as first recommended treatment. Of these 543 patients, 137 (25.2%) transitioned to helmet therapy after the condition did not improve over 4-8 weeks. In the remaining cases, RP/PT had already failed before the patients were seen in this program, and the starting treatment recommendation was CO. At the end of treatment, the measured improvements in ODD were 36.7%, 33.5%, and 15.1% for patients receiving CO, RP/PT/CO, and RP/PT, respectively. Orthotic treatment corresponded with the largest ODD change, while the RP/PT group had the least change in ODD. Earlier age at presentation corresponded with larger ODD change. The authors concluded that obtaining treatment at an earlier age as well as the type of treatment utilized impacts the degree of measured deformational head shape correction in positional plagiocephaly. This study suggests that treatment with a custom CO can result in more improvement in objective measurements of head shape.

Freudlsperger et al. (2016) conducted a retrospective cohort study to investigate the impact of starting age and severity on the effectiveness of helmet therapy. A total of 213 pediatric patients treated for positional plagiocephaly with an asymmetry were measured according to the Cranial Vault Asymmetry Index (CVAI) using 3D-Photogrammetry. Patients were classified by age at which treatment was started: Group 1 was comprised of patients < 24 weeks; Group 2, those aged 24-32 weeks; Group 3, those aged >32 weeks. Groups were also categorized by severity. Mean initial CVAI was 9.8%, which reduced to 5.4% after helmet treatment. Group 1 showed the highest absolute and relative rate of correction. Within the groups, severity correlated positively with relative and absolute reduction of the asymmetry. A significant difference in the reduction of the CVAI depending on age was only seen in moderate and severe cases of plagiocephaly, but not in mild plagiocephaly. The authors concluded the present study confirms the effectiveness of helmet therapy for positional plagiocephaly and that the use of an orthotic device is an appropriate treatment option particularly in infants with severe plagiocephaly and a start of helmet therapy before the age of 6 month is advisable.

Ho et al. (2016) conducted a retrospective cohort study using data from a single institution (2009-2012) to investigate the effectiveness of helmet therapy compared to no helmet therapy in the treatment of positional plagiocephaly in infants < 1 year of age. Participants included 171 infants with positional plagiocephaly (127 males, 44 females). Eighty-four patients received a helmet while 87 were not prescribed any therapy. The decision to initiate helmet therapy was made by the clinician based on the examination, parents' wishes, and recommendation of the orthotist. Mean age at the initial consultation was 7.38 months with an average follow-up length of 5.85 months. Those with helmets had a longer mean follow-up than those without (7.78 versus 3.85 months). In general, there was a reduction in overall plagiocephaly score regardless of whether or not the infant had helmet therapy. This suggests that while the cosmetic abnormalities resulting from positional plagiocephaly improved in both groups, those with helmets may have had a greater benefit. The authors concluded that there may be a role for helmet therapy in the treatment of positional plagiocephaly, particularly in those with severe cosmetic deformity. However, further randomized controlled trials are required to produce more conclusive evidence.

In a study of 1,050 infants, Couture et al. (2013) reported successful use of off-the-shelf helmet therapy. Infants with an Argenta classification type I (minimal deformity) were treated with repositioning while infants with an Argenta severity rating of II-V were treated with a helmet. Correction (overall rate of 81.6%) took longer in patients with an Argenta severity of III, IV, and V compared with Argenta type II, but was not significantly affected by age.

Kluba et al. (2011) enrolled 62 infants with severe positional plagiocephaly in a prospective cohort study. Twenty-four started helmet therapy before 6 months of age (group 1) and 38 were older than 6 months (group 2). Duration of therapy was significantly shorter in group 1 (14 weeks) compared with group 2 (18 weeks) with significantly better outcomes. The CVAI in group 1 was reduced to a normal mean value while infants in group 2 did not achieve normal values. The relative improvement in asymmetry was significantly better in group 1 (75%) compared with group 2 (61%). After 4 to 11 weeks of treatment, group 1 already showed a better absolute reduction and a better relative reduction. The authors concluded that optimal starting age for helmet therapy in infants with severe positional plagiocephaly is in months 5 to 6. They also conclude that delaying the onset of treatment significantly deteriorates the outcome.

Lipira et al. (2010) conducted a cohort study and used whole head 3D surface scans to compare outcomes of orthotic helmets and active repositioning in 70 infants with deformational plagiocephaly. Helmeted (N=35) and nonhelmeted/actively repositioned (N=35) infants were matched for severity of initial deformity. Change in mean and maximum asymmetry with treatment was the basis for group comparison. The helmeted group had a larger reduction than the repositioned group in both maximum (4.0% vs 2.5%) and mean asymmetry (0.9% vs 0.5%). The greatest difference was localized to the occipital region. The authors concluded that additional studies are needed to establish the clinical significance of these quantitative differences in outcome, define what constitutes pathologic head asymmetry, and determine whether superiority of orthotic treatment lasts as the child matures.

Graham et al (2005) conducted a cohort study to compare the effect of repositioning versus helmet therapy on CI in 193 infants referred for brachycephaly. Among the subgroup of 96 infants treated by repositioning from an average age of 4.6 - 7.7 months, the mean initial CI was 86.3% and the mean final CI was 85.7%. The change in CI was not significant. Among the subgroup of 97 infants treated with helmets from an average age of 6.0-10.3 months, the mean initial CI was 91.5% and the mean final CI was 88.4%. The change in CI for this group was significant. The authors concluded that implementation of helmet treatment at a younger age resulted in more improvement in the CI.

Professional Societies

American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)

Evidence-based guidelines were developed by a multidisciplinary task force comprised of the Joint Section on Pediatric Neurosurgery of the AANS and the CNS recommend the following regarding the management of pediatric positional plagiocephaly:

- Repositioning is an effective treatment for deformational plagiocephaly. However, there is Class I evidence from a single study and Class II evidence from several studies that repositioning is inferior to physical therapy and to use of a helmet, respectively.
- PT is recommended and is effective over repositioning alone for reducing the prevalence of infantile positional plagiocephaly in infants 7 weeks of age
- PT is as effective for the treatment of positional plagiocephaly and recommended over the use of a positioning pillow in order to ensure a safe sleeping environment and comply with American Academy of Pediatrics recommendations.
- Helmet therapy is recommended for infants with persistent moderate-severe plagiocephaly after a course of conservative treatment (repositioning and/or PT)
- Helmet therapy is recommended for infants with moderate to severe plagiocephaly presenting at an advanced age.

The task force stated that the while treatment of patients with plagiocephaly is non-surgical, neurosurgeons are frequently consulted with the objectives of ruling out craniosynostosis and determining whether the patient requires intervention, such as PT or the use of a molding helmet (Flannery et al., 2016).

American Academy of Pediatrics (AAP)

The AAP endorsed the evidence-based guidelines developed by the multidisciplinary task force comprised of the Joint Section on Pediatric Neurosurgery of the AANS and the CNS (2016).

Canadian Pediatric Society (CPS)

The CPS issued recommendations for the management of positional plagiocephaly. For the management of most children with mild or moderate positional plagiocephaly, the CPS recommends repositioning therapy plus PT as needed. Molding (helmet) therapy may be considered for children with severe asymmetry. The recommendations note that helmet therapy has been shown to influence the rate of improvement of asymmetry but not its final outcome. In addition, the CPS considers the evidence regarding the use of helmet therapy for the treatment of mild or moderate asymmetry insufficient (Cummings et al., 2011. Reaffirmed 2018).

There are multiple open clinical trials studying craniosynostosis. For more information, go to www.clinicaltrials.gov. (Accessed November 19, 2020)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Cranial orthoses are classified by the FDA as Class II devices. This classification requires special controls, including prescription use, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, and instructions for physicians and parents). They are intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The FDA has approved a large number of cranial orthoses. Additional information, under product code MVA, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 19, 2020)

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for plagiocephaly and craniosynostosis treatments. Local Coverage Determinations (LCDs/Local Coverage Articles (LCAs) exist; see the LCDs/LCAs for Cosmetic and Reconstructive Surgery. (Accessed November 5, 2020)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2021	Supporting Information • Updated *Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information • Archived previous version 2020T0031S

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.