PLAGIOCEPHALY AND CRANIOSYNOSTOSIS TREATMENT

Guideline Number: MMG102.K  Effective Date: October 1, 2020

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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 the following criteria are met:
  o Infant is between 3-18 months of age
  o Severe Plagiocephaly is present with or without torticollis
  o 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: See the Description of Services section for additional information regarding Anthropometric Measurements and Cephalic Index.

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.

Surgical Treatment

Medical notes documenting the following:

• History of medical conditions requiring treatment or surgical invention which includes all of the following:
  o To prove medical necessity, a well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment
  o 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
Required Clinical Information

Cranial Orthosis

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

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 orbitotragal depth; OR a Cephalic Index of at least 2 standard deviations above or below the mean for the appropriate gender/age.
Plagiocephaly a
procedures such as cranial vault remodeling and fronto
Surgical treatment of
craniosynostosis include increased intracranial pressure and abnormal brain development.
brain growth
Craniosynostosis requires surgical treatment to open the prematurely closed suture(s) in order to
from expanding to a n
of the skull where sutures remain open. This results in an abnormal shape of the skull, but does not prevent the brain
expansion of 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; Sheth; 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

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>21175</td>
<td>Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)</td>
</tr>
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HCPCS Code   Description
D5924      Cranial prosthesis
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 remodeling 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 do 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 cranial orthotic device (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; Sheth; 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., 2002).

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.

<table>
<thead>
<tr>
<th>Specifications for Taking Anthropometric Measurements</th>
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<tbody>
<tr>
<td><strong>Anthropometric Measure</strong></td>
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<tr>
<td>Cranial Vault</td>
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<tr>
<td>Skull Base</td>
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<td>Orbitotragial Depth</td>
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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).

<table>
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<th>Cephalic Index (AAOP, 2004)</th>
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<tr>
<td><strong>Gender</strong></td>
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The Cephalic Index is considered abnormal if it is 2 standard deviations above or below the mean measurements (Parkas 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).

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**CLINICAL EVIDENCE**

In an evidence review, Lam and Luerrszen stated that the management of positional skull deformation is nonsurgical. It involves ruling out craniosynostosis and determining the timing and need for intervention which includes repositioning, physical therapy (PT) and/or helmet orthosis. Repositioning education is effective in affording some degree of correction in virtually all infants with positional plagiocephaly. However, most studies suggest that a properly fitted helmet orthosis corrects asymmetry more rapidly and to a greater degree than repositioning. This is especially the case if the deformity is severe and if helmet therapy is applied during the appropriate period of infancy. The authors noted that there are no standardized criteria regarding the measurement and quantification of deformity or the most appropriate time window in infancy for treatment of positional plagiocephaly with a helmet. In general, infants with a more severe presenting deformity and infants helmented early in infancy tend to have better reported correction or even normalization of head shape. They concluded that the current commonly accepted management paradigm of positional plagiocephaly in infants can be justified (2018).

Lam et al. (2017) performed 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.

A 2018 Hayes report on published literature evaluating the use of CODs for treatment of positional cranial deformity yielded 20 low quality studies of varying types. The report concluded that the efficacy of this treatment is unclear.

Freudlsperger et al. (2016) investigated 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. 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 review on 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 and craniosynostosis.
plagiocephaly, particularly in those with severe cosmetic deformity. However, further randomized controlled trials are required to produce more conclusive evidence.

Lipira et al. (2010) 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.

In a study of 1050 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 longitudinal 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.

Graham et al. (2005) compared 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 89.1% 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.

CODs are accepted as treatment for positional cranial deformity by major organizations. This is likely due to the large number of trials encompassing a large study population that produced consistently positive outcomes with minimal reports of complications.

**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 Association of Neurological Surgeons (AANS)**

In a Patient Fact Sheet on craniosynostosis and craniofacial disorders, the AANS states that when it is indicated, most experts recommend surgical treatment between the ages of 3-8 months, depending on the case and surgical procedure. They state that early intervention is beneficial for several reasons, including prevention of further
deformities, the bones are most malleable at this age, bone re-growth is quicker and more likely, and rapid brain growth benefits from skull remodeling. However, the AANS does not specifically endorse any particular treatments or procedures specifically.

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 (Lam and Luerssen, 2016).

Canadian Paediatric 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 July 18, 2019)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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/pmncf. (Accessed July 18, 2019)

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Jimenez DF, Barone CM; Endoscopy-assisted wide-vertex craniectomy, “barrel-stave” osteotomies, and postoperative helmet molding therapy in the early management of sagittal suture craniosynostosis; Neurosurg Focus; 2000 Sep 15; 9 (3): e2.


National Institute of Neurological Disorders and Stroke (NINDS); Craniosynostosis Information Page; Last updated May 25, 2017.


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**GUIDELINE HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>10/01/2020</td>
<td><strong>Documentation Requirements</strong></td>
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<td>• Updated required clinical information</td>
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<td><strong>Supporting Information</strong></td>
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<td>• Archived previous policy version MMG102.1J</td>
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**INSTRUCTIONS FOR USE**

This Medical Management Guideline 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 benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, 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 Management Guideline is provided for informational purposes. It does not constitute medical advice.

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