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WellCare Prescription Insurance

Craniofacial Surgery

Policy Number: HS-268

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Revised Date(s): 8/6/2015; 9/27/2016; 7/6/2017; 6/7/2018; 3/7/2019, 9/5/2019

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Craniofacial surgery encompasses a broad spectrum of reconstructive procedures of the cranium and face. The objectives of these procedures are to correct deformities of the face and skull bones that result from birth defects, trauma, or disease and to restore craniofacial form and function by medical and surgical means. Some examples of conditions that may require craniofacial surgery are clefts of the lip and palate, craniosynotosis, hemifacial microsomia, microtia, Pierre Robin syndrome, Apert syndrome, and Crouzon syndrome.[1]

Craniosynotosis

The normal skull consists of several plates of bone that are separated by sutures. The sutures (fibrous joints) are found between the bony plates in the head. As the infant grows and develops, the sutures close, forming a solid

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piece of bone, called the skull. Craniosynostosis is a condition in which the sutures close too early, causing problems with normal brain and skull growth. Premature closure of the sutures may also cause the pressure inside of the head to increase and the skull or facial bones to change from a normal, symmetrical appearance. The condition occurs in one out of 2,200 live births and affects males slightly more often than females. Craniosynostosis is most often sporadic (occurs by chance). In some families, craniosynostosis is inherited and is a feature of many different genetic syndromes that have a variety of inheritance patterns and chances for reoccurrence, depending on the specific syndrome present.[2, 5]

The involved suture and anatomical name is listed below for the types of craniosynostosis:[6,7,8,9,10]

1. **Primary.** Primary craniosynostosis (PC) is a general term for the improper development of the bones of the skull, which can result in an abnormal head shape in affected individuals. Severity of PC varies in patient to patient, although intelligence is usually unaffected. PC may occur as an isolated finding or as part of a syndrome. The main treatment is surgery, but not all affected children will require surgery. The exact cause of PC is unknown, although the skull abnormalities result from the abnormal hardening (ossification) of the cranial sutures. PC is distinguished from secondary craniosynostosis (SC), which occurs because of a primary failure in brain growth.[10]

2. **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

3. **Compound craniosynostosis** classifications include:
   - **Nonsyndromic.**
     - *Bicoronal*
   - **Syndromic.** In addition to craniofacial malformations, syndromic craniosynostosis involves multiple systems (e.g., cardiac, genitourinary, musculoskeletal). Many patients have a family history of abnormal head shape. Clinical examination of infants with craniofacial malformations should include careful evaluation of the neck, spine, digits, and toes. Crouzon's disease and Apert's syndrome occur more frequently than the other syndromes associated with craniosynostosis.[6]

     - *Crouzon's disease* is a birth defect characterized by abnormalities in the skull and facial bones, caused by a fusing of both sides of the coronal suture; it often causes the skull to be short in the front and the back. Flat cheek bones and a flat nose are also typical of this disorder.[7] Crouzon's disease is inherited through an autosomal-dominant pattern; nearly 60 percent of cases are new mutations, and many are associated with paternal age older than 35 years. Crouzon's disease occurs in one of every 25,000 live births and accounts for 5 percent of cases of craniosynostosis. Nucleotide alterations causing amino-acid substitutions at the FGFR2 gene on chromosome 10 lead to the Crouzon phenotype. Clinical findings include brachycephalic craniosynostosis, significant hypertelorism, proptosis, maxillary hypoplasia, beaked nose and, possibly, cleft palate. Intracranial anomalies include hydrocephalus, Chiari 1 malformation, and hind-brain herniation (70 percent). Pathology of the ear and cervical spine is common. Infants with Crouzon's disease do not have anomalies of the hands and feet as do infants with Apert's syndrome.[6]

     - *Apert's syndrome* (acrocephalosyndactyly) is a autosomal dominant disorder and craniofacial abnormality characterized by an abnormal head shape, small upper jaw, and fusion of the fingers and toes.[7] It is caused by nucleotide alterations resulting in amino-acid substitutions, leading to a mutation in the FGFR2 gene located on chromosome 10. Craniosynostosis and symmetric syndactyly of the extremities are hallmarks of this syndrome. Clinical features include misshapen

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skull caused by coronal suture synostosis, wide-set eyes, mid-face hypoplasia, choanal stenosis, and shallow orbits. Intracranial anomalies include megalocephaly, hypoplastic white matter, and agenesis of the corpus callosum, leading to cognitive impairment. Cardiac anomalies, including atrial septal defect and ventricular septal defect, and renal anomalies such as hydronephrosis occur in 10 percent of these patients. It occurs in one of every 160,000 live births. [6]

- *Pfeiffer's syndrome* is a birth defect characterized by abnormalities of the skull, hands, and feet; it results in wide-set, bulging eyes, an underdeveloped upper jaw, and a beaked nose due to the head being unable to grow normally. [7]
- *Saethre-Chotzen syndrome* is a birth defect characterized by an unusually short or broad head. In addition, the eyes may be spaced wide apart and have droopy eyelids, and fingers may be abnormally short and webbed. [7]
- *Brachycephaly* is a birth defect characterized by the disproportionate shortness of the head and is caused by a premature fusing of the coronal suture. It is commonly associated with a number of syndromes, such as Apert's, Crouzon's, Pfeiffer's, Saethre-Chotzen, and Carpenter's. Deformational brachycephaly can also occur from infant positioning during sleep. [7]

4. Other

- **Multiple sutures*.** pansynostosis (all), oxycephaly (conical), acrocephaly (pointed), turricephaly or turmschadel (tower), cloverleaf skull or kleeblattschadel
- **Encephalocele:** Characterized by a protrusion of the brain or its coverings through the skull. [7]
- **Kleeblattschadel syndrome:** A birth defect characterized by abnormalities of the skull and facial bones. It is caused by a premature fusing of the fibrous sutures. Also called "cloverleaf skull." [7]
- **Oxycephaly:** A birth defect characterized by abnormalities in the skull and facial bones. This syndrome causes the top of the skull to be pointed or cone-shaped. It is caused by a premature fusing of the coronal and sagittal sutures. Also known as turricephaly or high-head syndrome. [7]
- **Pierre Robin syndrome:** A birth defect characterized by abnormalities in the facial bones, resulting in a smaller than normal lower jaw or receding chin. The tongue often falls back in the throat causing difficulty breathing. [7]
- **Torticollis:** Also known as wryneck, is a twisting of the neck that causes the head to rotate and tilt at an odd angle. It most often results from tightness of one of the neck muscles.

Indications and Contraindications to Intervention

In addition to the optimization of the growth potential of the brain in the early perinatal period, additional indications for surgical intervention in members with craniosynostosis include prevention of:[4]

- Intracranial hypertension and its associated sequelae that occur in some with uncorrected synostosis
- Progression of the calvarial deformity
- Progression of the facial deformity

Surgery is advocated in early infancy because most brain growth occurs in the first year of life. Therefore, if the deformed sutures are not released, the deforming vectors of the continually growing brain result in progression of the deformity with increasing age. The osseous defects following surgery undergo reossification more completely if surgery is performed in those younger than 1 year compared with later. The calvarium in an infant aged 3-9 months is much more malleable, making it easier to shape and providing a better outcome.[4]

The only absolute contraindication to surgical intervention is the presence of microcephaly. Calvarial sutures close secondary to the lack of expansile force from the underlying brain. Surgical intervention just to release the fused sutures is associated with high rate of re-fusion and thus is not appropriate. Although surgery for craniosynostosis improves calvarial shape, it should not be considered cosmetic.[4]

The key to treating craniosynostosis is early detection and treatment. Some forms of craniosynostosis can affect the brain and development of a child. The degree of the problems is dependent on the severity of the craniosynostosis,

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the number of sutures that are fused, and the presence of brain or other organ system problems that could affect the child. Genetic counseling may be recommended by the physician to evaluate the parents of the child for any hereditary disorders that may tend to run in families. A child with craniosynostosis requires frequent medical evaluations to ensure that the skull, facial bones, and brain are developing normally. The medical team works with the child's family to provide education and guidance to improve the health and well-being of the child.[3]

Surgical Options

Traditional procedures involve some form of open surgery to remove the fused suture and remodel the skull, using plates and screws as necessary. These operations are usually recommended in infants 6 to 8 months of age, are lengthy (4-8 hours in duration), and can require postoperative hospitalization for 4 to 8 days. Confirmation of diagnosis and presurgical evaluation requires a multidisciplinary team that may involve geneticists, pediatric neurologists, plastic surgeons, neurosurgeons, endocrinologists, and ophthalmologists.[5]

Endoscopic surgery, such as endoscopy-assisted strip craniectomy or suturectomy, is less invasive than open cranial vault reconstruction and is best performed when the infant is younger than 6 months old. The surgeon uses an endoscope to remove the fused suture(s), which allows the growing brain to expand. After surgery, the infant wears a customized helmet that helps to mold the skull into a proper shape as the brain grows. A pediatric neurosurgeon or plastic surgeon makes two incisions in the scalp over either end of the fused suture, and a dissecting space is created beneath the scalp in a bloodless fashion using a rigid endoscope and an electrocautery device. The surgeon incises the skull at each end of the suture, and after separating the dura (tough outer membrane covering the brain) from the overlying skull, makes two more incisions to form a rectangular strip. This strip of bone containing the fused suture is removed through the scalp incisions in one or two pieces. The operation normally lasts between 1 and 2 hours and most patients are discharged in 1 to 2 days. Within 1 week of surgery, the infant is fitted with a customized helmet that applies pressure on abnormal bulges in the skull, but allows for expansion in the correct direction. The helmet helps to guide the expanding skull to a normal shape over 11 to 12 months. Most patients typically need one or two helmets during the treatment period. Follow-up appointments occur every 2 to 3 months.[5]

Children with syndromic deformities require careful follow-up into adulthood because they may develop recurrent stenosis and/or raised intracranial pressure from other causes (e.g., hydrocephalus, hindbrain hernia). Papilledema, if present initially, may herald a recurrence if seen on follow-up. Children with syndromic forms of craniosynostosis (e.g., Crouzon or Apert syndrome) can be affected by a variable degree of developmental delay. Long-term care and surveillance by an integrated neurosurgical and craniofacial multidisciplinary team is essential.[8]

Surgical interventions in non-syndromic craniosynostosis include:[6]

- *Sagittal Synostosis*. Involves either strip craniectomy or cranial vault remodeling with excision of the frontal, parietal, and occipital bones, which are trimmed, reshaped, and affixed with absorbable plates. Recently, minimally invasive endoscopic strip craniectomy, which involves significantly less blood loss and a shorter hospital stay, has been successful.
- *Coronal Synostosis.* Objective is to increase anteroposterior dimensions of the calvaria.
- *Metopic Synostosis.* Objective is to increase the volume of the anterior cranial fossa.

The management of craniofacial syndromes includes correction of craniosynostosis between three and six months of age, and correction of limb defects between one and two years of age. When the patient is a young adult, surgeries to normalize appearance and correct malocclusion are done.

Potential intraoperative complications include massive blood loss and air embolism. Mortality rates are low according to recent reports. Careful follow-up of the patient is necessary after surgery to ensure that the sutures do not re-fuse. Postoperative monitoring of head circumference and checking for signs and symptoms of increased intracranial pressure are necessary.

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General Principles of Surgical Repair

Metopic synostosis is characterized by trigonocephaly. The forehead appears ridged, and the patient has hypotelorism and proptosis. This condition is repaired by advancing the orbital rims, which are noted to be recessed, in addition to removing the fused metopic suture. The forehead requires careful reconstruction. Some institutions perform an endoscopic strip suturectomy through a small incision and then helmet the child to reshape the head as the child grows.[8]

Sagittal synostosis is characterized by a skull that is long and narrow. Correction requires reconstruction of the skull so that it is shorter and wider. One factor that must be taken into account during preoperative planning and repair is compensatory growth, which can be anterior, posterior, or both. Frontal bossing can be quite significant, particularly when compensatory growth is anterior. Surgical goals are to shorten and widen the skull. Additionally, a bifrontal craniotomy is required to correct the frontal bossing. In similar fashion, if the compensatory growth involves the occipital bone, then an occipital craniotomy is required. If compensation involves both the frontal and occipital bones, then surgery often needs to be performed in a modified prone position and should include both a bifrontal and occipital craniotomy.[8]

Unilateral coronal synostosis produces a forehead that is typically bossed on one side and recessed on the other. In this case, a bifrontal craniotomy is required with reconstruction of the frontal bone. In particular, the bossed area needs to be recessed and reduced. An orbital rim advancement is also required.[8]

Bilateral coronal synostosis produces a skull that is excessively tall and short. The surgery to correct this should produce a skull that is longer in the anterior-posterior dimension and shorter in the superior-inferior dimension. As with the unilateral coronal synostosis case, an orbital rim advancement is required.[8]

Ongoing Treatment and Evaluation

Long-term care and surveillance by an integrated neurosurgical and craniofacial multidisciplinary team is essential.[8] A child with craniosynostosis requires frequent medical evaluations to ensure that the skull, facial bones, and brain are developing normally. The medical team works with the child's family to provide education and guidance to improve the health and well-being of the child.[3]

POSITION STATEMENT

Applicable To:

- ☑ Medicaid (excluding AZ, NC, KY)
- ☑ Children's Medical Services Health Plan (CHIP)

Refer to *HS 009: Cranial Remodeling With Orthotic Devices* for coverage information on protective, soft, or prefabricated helmets for children.

Exclusions

Craniofacial surgery is not covered when it is performed for cosmetic reasons, rather than primarily to restore impairment or correct deformity in children, caused by injury, disease, birth defects, or growth and development.[1]

Medical Necessity Criteria

Craniofacial Surgery **is considered medically necessary** based on the following:

1. For craniofacial surgery, “medical necessity” is defined as the reason the procedure is needed to raise a beneficiary to his or her optimal functioning level or, specific to children, to correct or ameliorate significant congenital craniofacial deformities.[1]

2. The need for surgery must arise from an injury, disease, birth defect, or growth and development that resulted in significant functional impairment.[1]
“Significant functional impairment” may include, but is not limited to

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1. Problems with communication.
2. Problems with respiration.
3. Problems with eating.
4. Problems with swallowing.
5. Visual impairments.
6. Distortion of nearby body parts.
7. Obstruction of an orifice.

3. Orthognathic surgery prior to craniofacial surgery is provided for persistent difficulties with mastication and swallowing, jaw posturing, temporomandibular joint problems, and malocclusion needing skeletal correction.[1]

The following information shall be submitted with each prior approval request:[1]

1. The location and cause of the defect.
2. Pre-operative photographs.
3. CPT codes describing the procedures to be performed.
4. Supporting documentation that the treatment can reasonably be expected to improve the impairment.

CODING

Covered CPT®* Codes

21175 Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
61550 Craniectomy for craniosynostosis; single cranial suture
61552 Craniectomy for craniosynostosis; multiple cranial sutures
61556 Craniotomy for craniosynostosis; frontal or parietal bone flap
61557 Craniotomy for craniosynostosis; bifrontal bone flap
61558 Extensive craniectomy for multiple cranial suture craniosynostosis (eg, cloverleaf skull); not requiring bone grafts
61559 Extensive craniectomy for multiple cranial suture craniosynostosis (eg, cloverleaf skull); recontouring with multiple osteotomies and bone autografts (e.g., barrel-stave procedure) (includes obtaining grafts)
21120 Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121 Genioplasty; sliding osteotomy, single piece
21122 Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
21123 Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125 Augmentation, mandibular body or angle; prosthetic material
21127 Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137 Reduction forehead; contouring only
21138 Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139 Reduction forehead; contouring and setback of anterior frontal sinus wall
21141 Reconstruction midface, LeFort I; single piece, segment movement in any direction (eg, for Long Face Syndrome), without bone graft
21142 Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, without bone graft
21143 Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, without bone graft
21145 Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)
21146 Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)
21147 Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)
21150 Reconstruction midface, LeFort II; anterior intrusion (eg, Treacher-Collins Syndrome)
21151 Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)
21155 Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I
21159 Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I

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21160 Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I
21193 Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21194 Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)
21195 Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21196 Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21198 Osteotomy, mandible, segmental;
21199 Osteotomy, mandible, segmental; with genioglossus advancement
21206 Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)
21208 Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209 Osteoplasty, facial bones; reduction
21210 Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21215 Graft, bone; mandible (includes obtaining graft)
21230 Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
21244 Reconstruction of mandible, extraoral, with transosteal bone plate (eg, mandibular staple bone plate)
21245 Reconstruction of mandible or maxilla, subperiosteal implant; partial
21246 Reconstruction of mandible or maxilla, subperiosteal implant; complete
21247 Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)
21255 Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)
21256 Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)
21260 Periorbital osteotomies for orbital hypertelorism, with bone grafts; extracranial approach
21261 Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach
21263 Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement
21267 Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; extracranial approach
21268 Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach
21270 Malar augmentation, prosthetic material
21275 Secondary revision of orbitocraniofacial reconstruction
21295 Reduction of masseter muscle and bone (eg, for treatment of benign masseteric hypertrophy); extraoral approach
21296 Reduction of masseter muscle and bone (eg, for treatment of benign masseteric hypertrophy); intraoral approach
21172 Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21179 Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180 Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21181 Reconstruction by contouring of benign tumor of cranial bones (eg, fibrous dysplasia), extracranial
21182 Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm
21183 Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm
21184 Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm
21188 Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes obtaining autografts)
21235 Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)
21280 Medial canthopexy (separate procedure)
21282 Lateral canthopexy

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21175 Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)

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61558 Extensive craniectomy for multiple cranial suture craniosynostosis (eg, cloverleaf skull); not requiring bone grafts
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Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
9/5/2019	• Approved by MPC. Updated criteria to include NC.
3/7/2019	• Approved by MPC. Criteria for orthotic devices removed as a duplicate.
6/7/2018, 7/6/2017, 9/27/2016	• Approved by MPC. No changes.
8/6/2015	• Approved by MPC. Clarified language re: coverage for members regardless of age when criteria met.
11/6/2014	• Approved by MPC. New.