Name of Policy:
Dynamic Orthotic Cranioplasty (DOC)

Policy #: 008  Latest Review Date: May 2007
Category: Durable Medical Equipment  Policy Grade: D

Background:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, if customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:
1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Coding:
HCPCS code: S1040  Cranial remolding orthosis, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

Effective for dates of service on or after January 1, 2007:
S1040  Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

Description of Procedure or Service:
Dynamic Orthotic Cranioplasty (DOC) involves the use of a custom molded orthotic, either a helmet or band that can progressively mold the shape of the skull. This treatment is typically initiated around 5-6 months of age and continues for an average of 4 to 5 months. Both helmets and cranial bands are recommended for wear 23 hours per day with an hour off for exercise and skin care.
Plagiocephaly is a condition in which the head is asymmetrically shaped. This may be subdivided into two categories. Synostotic plagiocephaly is due to the premature closing of sutures of the cranium or skull. Non-synostotic plagiocephaly is asymmetry of the head or skull when the sutures of the cranium or skull remain open. This is sometimes called positional plagiocephaly or deformational plagiocephaly. It can be caused by environmental factors including, but not limited to premature birth, restrictive intrauterine environment, birth trauma, torticollis, cervical anomalies, and positioning of the baby’s head while sleeping.

Policy:
For dates of service prior to August 24, 2004, dynamic orthotic cranioplasty (DOC) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all the following criteria are met:
1. Physical exam and radiographic studies demonstrate significant functional deformity of the orbits and/or temporomandibular joint related to plagiocephaly (ICD-9 code: 754.0).
2. Caregivers are capable of maintaining and monitoring the device.

Documentation for review should include a complete history and physical assessment, consultation recommendations, x-ray, CT scans and radiologist reports, and complete neurological evaluation. Cases determined not medically necessary would be considered cosmetic.

For dates of service on or after August 24, 2004, dynamic orthotic cranioplasty meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for:

1. Infants age **5-8 months**:
   - who have positional plagiocephaly with asymmetry of the cranial base, cranial vault, or orbitotragial distance resulting in facial and/or ear deformities documented by photographs looking down on the top of the infant’s head (superior view)(see figure 1); and
   - who have failed a 2 month trial period of conservative treatment of head repositioning, “tummy time”, or physical therapy (see Key Points)

2. Infants **over age 8 months to 12 months**:
   - who have positional plagiocephaly with asymmetry of the cranial base, cranial vault, and/or orbitotragial distance resulting in facial and/or ear deformities documented by photographs made looking down on the top of the infant’s head (superior view)(see figure 1).
Dynamic orthotic cranioplasty does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for infants over age 12 months.

Dynamic orthotic cranioplasty (DOC) does not meet Blue Cross Blue Shield of Alabama’s medical criteria for coverage for patients including, but not limited to the following:

1. When it is performed for cosmetic correction of positional plagiocephaly. DOC for treatment of positional plagiocephaly without severe functional impairment is considered cosmetic, and not medically necessary.
2. DOC is not considered medically necessary for treatment of synostotic plagiocephaly (surgical treatment is required).
3. DOC is not considered medically necessary as an adjunctive postsurgical therapy for synostotic plagiocephaly.

The purpose of Blue Cross and Blue Shield of Alabama’s medical policy is to provide a guide to coverage. Medical policy is not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Key Points:
In 1992, the American Academy of Pediatrics (AAP) initiated the “Back to Sleep” campaign recommending that infants be placed to sleep in the supine position to reduce the incidence of sudden infant death syndrome (SIDS). While the rate of SIDS decreased from 1992 to 2000, the practice of placing an infant on its back during sleep can result in flattening of the occipital area.
of the skull. The incidence of positional head deformity is estimated to have risen fivefold since 1992, and the condition now may occur in one of every 60 live births.

The diagnosis of deformational plagiocephaly in infancy is made primarily on the basis of history and confirmed by physical examination. It is important for the physician to look down at the top of the infant’s head to view the position of the ears, and note the position of the cheekbones (zygomas). When using this technique, the examiner can observe if the typical deformational plagiocephaly, which forms a parallelogram can be observed. In addition to the usually unilateral flattening of the occipital area, there may be ipsilateral frontal (forehead) and parietal bossing, cheekbone prominence, and anterior ear displacement ipsilateral to the flattened occiput. When the infant’s face is examined, abnormalities such as head tilt and contralateral facial flattening may be detected. Neck movements should be assessed to determine of torticollis is present.

The 2003 AAP Prevention and Management of Positional Skull Deformities in Infants policy statement recommends the following treatments for deformational plagiocephaly:

“Management of deformational plagiocephaly involves preventive counseling of parents, mechanical adjustments, and exercises. Parental compliance with the management plan is pivotal in lessening the likelihood and severity of skull deformity. Skull molding helmets are an option for patients with severe deformity or skull shape that is refractory to therapeutic physical adjustments and position changes. Surgery is rarely necessary but may be indicated in severe refractory cases of deformational plagiocephaly or in patients with craniosynostosis.

Preventive Counseling
To prevent the deformity, parents should be counseled during the newborn period (by 2 to 4 weeks of age) when the skull is maximally deformable. Parents should be instructed to lay the infant down to sleep in the supine position, alternating positions (ie, left and right occiputs). When awake and being observed, the infant should spend time in the prone position. The infant should spend minimal time in car seats (when not a passenger in a vehicle) or other seating that maintains supine positioning. Once deformational plagiocephaly has developed, these same preventive strategies may be used to minimize progression. Additionally, it is important to monitor head shape closely until there is confidence that improvement will continue, usually when the infant is old enough to sit, crawl, and spend less time on his or her back, and until any associated torticollis is completely corrected.

Mechanical Adjustments and Exercises
Once deformational plagiocephaly is diagnosed; the parent should be made aware of the condition and the mechanical adjustments that can be instituted. In general, most infants improve if the appropriate measures are conducted for a 2- to 3-month period. These include positioning the infant so that the rounded side of the head is placed dependent against the mattress. Additionally, the position of the crib in the room may be changed to require the child to look away from the flattened side to see the parents and others in his or her room. The pediatrician should continue to encourage supervised "tummy time" on firm surfaces when the infant is awake and being observed. Torticollis perpetuates the position of the head on the flattened side and can add to a greater facial deformity. Therefore, if torticollis is present, neck motion exercises should be taught to the parents as part of management. Neck exercises should be done with each diaper change. There are 3 repetitions per exercise, and it is estimated to take approximately 2
additional minutes per diaper change. One hand is placed on the child’s upper chest, and the other hand rotates the child’s head gently so that the chin touches the shoulder. This is held for approximately 10 seconds. The head is then rotated toward the opposite side and held for the same count. This will stretch out the sternocleidomastoid. Next, the head is tilted so that the infant’s ear touches his or her shoulder. Again, the position is held for a count of 10 and repeated for the opposite side. This second exercise stretches the trapezius muscle. Additionally, the parents may be taught the rotating chair or stool technique to enhance neck motion in the infant.”

The health outcomes of untreated plagiocephaly without synostosis (PWS) are uncertain. There are no published data on the effects of PWS on neuropsychological deficits, developmental delay, temporomandibular joint disorders, or psychosocial concerns related to a perceived abnormal appearance. The major reason for intervention is to optimize the cranial contour to achieve an acceptable appearance, not to prevent or correct adverse developmental consequences.

The natural history of PWS is not well documented. Remarkably few adults have deformities of cranial symmetry of shape, suggesting that the abnormality is either self-correcting or effectively masked by a combination of increased cranial circumference and hair growth.

There are no randomized studies that directly compared treatment modalities for PWS. The available studies were either non-randomized weakly controlled comparisons or uncontrolled case series. Because little information exists about the true risk of leaving PWS untreated, it is difficult to compare treatment techniques, since a treatment effect cannot be reliably differentiated from spontaneous recovery. The available data do not clearly support one-treatment techniques as superior to another or a superior to no treatment. Moreover, the degree of cranial asymmetry that constitutes an abnormality warranting intervention versus normal human variation cannot be determined from the available data.

In most situations, an improvement to repositioning and neck exercise is seen over a two-to-three-month period if these measures are instituted as soon as the conditions is recognized.

In his study, Moss suggests that repositioning infants may produce improvement in mild to moderate cases similar to improvements achieved with extremal orthotic devices. However, Mulliken et al linked the use of helmets with an improvement over that achieved by repositioning alone. The best response for helmets occurs in the age range of four to twelve months because of the greater malleability of the infant skull bone and the normalizing effect of the rapid growth of the brain. There is less modification of the cranial configuration when used after 12 months of age. The use of helmets and other related devices seems to be beneficial primarily when there has been a lack of response to mechanical adjustments and exercises.

May 2007 Update
No new published peer-reviewed literature was located that would alter the coverage statement of this policy.
**Key Words:**

**Approved by Governing Bodies:**
FDA ruled May 29, 1998 classifying cranial orthotics used for treatment of deformational plagiocephaly as class II, neurology devices. As a class II device, the FDA has identified special controls required to ensure their safe and effective use and requires submission of a 510(k) prior to placing these devices on the market.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Covered if covered by the Participating Home Plan
BellSouth contracts: No special requirements
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.
Wal-Mart: Special benefit consideration may apply. Refer to member’s benefit plan.
Pre-certification: Not required
Pre-determination: Done at request of provider and/or subscriber

**References:**

Policy History:
Medical Policy Group, July 2001
Medical Policy Administration Committee, August 2001
Medical Policy Group, July 2003 (1)
Medical Policy Group, May 2005 (2)
Medical Policy Administration Committee, May 2005
Available for comment June 2-July 13, 2005
Medical Policy Group, May 2007 (1)

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plans contracts.