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Title:

Cranial Remolding Orthosis (CRO) Device

Number:

DME103.007

Effective Date:

07-01-2005

Legislation:

ILLINOIS: None

NEW MEXICO: None

TEXAS: There is a legislative mandate adopted by the Texas Department of Insurance regarding required coverage of craniofacial abnormalities for children who are younger than 18 years of age. The mandate stipulates provision of benefits for reconstructive surgery to improve the function of, or to attempt to create a normal appearance of, an abnormal structure. Congenital defects, developmental doformities, trauma, tumors, infections, or disease may cause an abnormal structure. As an adjunctive postsurgical therapy for synostotic plagiocephaly, a CRO device, therefore, is allowed.

FEDERAL (applies to all Plans): None

Contract:

Check all contract provisions.

Coverage:

As a non-surgical treatment of non-synostotic positional plagiocephaly, a CRO device **will be eligible for coverage** when banding is initiated at four (4) to eighteen (18) months of age for moderate to severe positional head deformities. All requests seeking coverage (if there are no benefit restrictions) of a CRO device for a non-surgical indication must include all required documentation before a medical necessity determination can be made:

- Failed conservative therapy of no less than two (2) months by:
 1. Repositioning the infant's head to the opposite of the infant's preferred position when either lying down, reclined, or sitting; and
 2. Performing neck exercises at each diaper change; and
 3. Repositioning the infant's bed encouraging the infant to look away from the flattened side to view individuals in the room; and,
- Either one of the following sets of measurements or indications:
 1. Asymmetrical appearance confirmed by a right/left discrepancy of greater than six (6) millimeters in any craniofacial anthropometric measurement; or
 2. Brachycephalic or Dolichocephalic disproportion (comparison of head length versus head width) confirmed by a cephalic index of two (2) standard deviations above mean or two (2) standard deviations below mean; and
- Photographic evidence supporting the moderate to severe non-synostotic positional plagiocephaly.

NOTE: Measurements are usually obtained by the physician or orthotist fitting the helmet or headband.

As an adjunctive postsurgical therapy for synostotic plagiocephaly or hydrocephalus, a CRO device may be considered medically necessary.

Codes:

CPT Codes:	HCPCS Codes:
97799	S1040
Deleted Codes Effective 1/2006: 97703	

ICD-9 Diagnosis Codes:	ICD-9 Procedure Codes:
754.0, 756.0, V45.89, V48.6, V58.9	93.29

Description:

The **Cranial Remolding Orthosis (CRO) or Craniofacial Orthosis Device** is a headband (helmet) appliance used to treat variable degrees of cranial asymmetry or abnormal head shape, known as plagiocephaly, by redirecting growth. These abnormalities are due to premature fusion of the seams between the bony plates of the skull known as synostotic plagiocephaly (craniosynostosis) OR non-synostotic plagiocephaly (open sutures) known as positional or deformational plagiocephaly. These positional conditions or misshapen appearance can be derived from environmental factors such as:

- Premature birth,
- Restrictive intrauterine environment,
- Birth trauma,
- Shortening of the sternocleidomastoid neck muscle (known as torticollis),
- Cervical anomalies,
- Medical treatment, such as long-term hyperalimentation, requiring constant head positions for catheter placement,
- Sleeping positions, or
- From the interaction of any of these conditions.

In effect, the continuous pressure on one side of the cranium causes all the bones on the same side to progress forward, creating asymmetry and sometimes a realignment of the facial structures as well.

Infants with hydrocephalus have an abnormal excessive accumulation of cerebrospinal fluid (CSF) resulting in the dilation of the cerebral ventricles of the brain caused by a disturbance in CSF circulation or an over-production of CSF. Hydrocephalus raises the intracranial pressure and results in abnormal head enlargement with possible brain atrophy. A CRO device may be used in conjunction with surgical treatment of hydrocephalus.

Infants with positional plagiocephaly may exhibit complex and multiple asymmetries affecting the cranial vault, skull base, and face, such as unilateral flattening or bossing (protruding) of head areas with or without head tilting. The first step in determining whether a CRO device is needed is to complete craniofacial anthropometric measurements and calculate the cephalic index, in addition to standard or routine measurements of the head circumference. The measurements may be done manually or by use a specialized scanner.

The **craniofacial anthropometric measurement** of the head (skull and face) is the comparison of right and left sides by measuring the distance in millimeters (mm) from one side of the face or skull to another. The primary areas measured and asymmetry (a discrepancy of 6 to 12 mm) is calculated, as shown in the following table:

Craniofacial Area	Anthropometric Measurement	Determines Asymmetry	Calculated
Cranial (skull) base	from right and left subnasal (<u>sn</u>) point (midline under the nose) to tragus (<u>t</u>) (the cartilaginous projection in front of the external auditory canal)	upper jaw depth or right and left face height	<u>sn</u> to left <u>t</u> minus <u>sn</u> to right <u>t</u>
Cranial vault	from right and left frontozygomaticus (<u>fz</u>) point (forehead just above the eye orbit) to right and left euryon (<u>eu</u>) (most lateral point of the head)	bones of the skull enclosing the brain	left <u>fz</u> to right <u>eu</u> minus right <u>fz</u> to left <u>eu</u>
Orbitotragial depth or distances	from right and left exocanthion (<u>ex</u>) point (outer point of the eye where the eyelids meet) to tragus (<u>t</u>)	cheek bones below the eyes	left <u>ex</u> to left <u>t</u> minus right <u>ex</u> to right <u>t</u>

The cephalic index is the ratio of the width of the head to its length, using head width measurement from euryon (eu) on one side of head to euryon (eu) on other side of head versus head length measurement from glabella (g) point to opisthocranium (op). Expressed in a percentile number, the cephalic index is calculated by head width multiplied by 100 and divided by head length, as shown in the following equation:

$$\text{Head width (eu to eu) x 100 divided by Head length (g to op)}$$

The cephalic index is considered abnormal (the head shape may not be asymmetrical) if it is two standard deviations (SD) above or below the mean measurements (mean being appropriate to gender/age). Therefore, cephalic indices are categorized as a measurement of:

- Above 80 is considered being brachycephalic or broad (head width wider for head length);
- Between 75 and 80 is considered being mesocephalic (head of medium width and length); and,
- Below 75 is considered being dolichocephalic or long (head width narrow for head length).

The ± standard deviations with the mean of cephalic indices are shown on the following table:

Gender	Age	- 2 SD	- 1 SD	Mean	+ 1 SD	+ 2 SD
Male	16 days to 6 months	63.7	68.7	73.7	78.7	83.7
	6 to 12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days to 6 months	63.9	68.6	73.3	78.0	82.7
	6 to 12 months	69.5	74.0	78.5	83.0	87.5

The cranial index is the same ratio taken on the skull.

The CRO device has also been proposed as a postoperative complement for those patients undergoing surgery for synostotic plagiocephaly or hydrocephalus.

The CRO device is customized to the patient's head shape. It is fabricated, from either a plaster of Paris impression or by computer models from scanned measurements, using a semi-rigid outer shell bonded to a foam inner lining. This

lightweight cranial headband applies dynamic pressure to the elevated areas, while leaving space for growth and remodeling of the flattened areas. The average treatment timeline using a CRO device is approximately four (4) to five (5) months and is typically initiated around five (5) to six (6) months of age. Both helmets and cranial bands are recommended for wear 23 (twenty-three) hours per day. As the infant ages, the helmet or band will require adjustments or replacement to accommodate the cranial growth. Throughout the treatment course, the head shape may be compared to a computer model from the manual or scanned measurements. An exit head casting is done at the completion of the therapy course.

The CRO device is known by several different names, such as:

- DOC Band™ (Dynamic Orthotic Cranioplasty Band),
- STARband™ or STARlight™,
- PAP Orthosis (Plagiocephalic Applied Pressure Orthosis),
- CSO (Cranial Solutions Orthosis),
- Cranial Shaping/Molding Helmet,
- Cranial Band,
- Cranial Symmetry System,
- CranioCap™.

Rationale:

Although there is limited published data from uncontrolled case series, the literature describes the effectiveness of the CRO device as a nonsurgical alternative or as an adjunctive to infant cranial surgery. In order to validate the treatment, a controlled group case series is considered particularly important to compare outcomes since mild positional molding may self-correct over time or become inapparent due to hair growth. One needs only to examine the heads in the adult population to realize that the number of appreciable asymmetry is far less in this age range than in the neonatal population. The deduction is that the natural remodeling process of the human head must correct many of the deformities seen in childhood. Repositioning has been shown to be as effective in restoring symmetry to the cranium.

There are case studies of infants with mild to moderate abnormalities exhibiting successful correction of asymmetries when using a CRO device. Moderate to severe abnormalities may require a combination use of surgery and a CRO device to prevent regression of the repair post-operatively. Positional plagiocephaly does not pose a threat to the child's physical health. There are no published data on the effects of positional plagiocephaly 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 incidence of positional plagiocephaly has increased rapidly in recent years as a result of the "Back to Sleep" campaign recommended by the American Academy of Pediatrics (AAP), in which a supine sleeping position is recommended to reduction of the risk of sudden infant death syndrome (SIDS). It is estimated that one of every 60 (sixty) newborns may have some degree of plagiocephaly.

There are three (3) basic options for treating plagiocephaly:

- No therapy,
- Repositioning (increased "tummy time") therapy, or
- Helmet or Cranial band orthosis therapy.

Helmet or cranial band orthosis is generally considered after a failure of an initial trial of repositioning. However, some providers recommend early helmet or cranial banding earlier on older infants as the orthosis therapy may be increasingly

less effective in the older infant when their cranial sutures begin to close. Therefore, requiring a two (2) month trial of repositioning therapy in children older than six (6) to nine (9) months may limit the effectiveness of the helmet or cranial band therapy. Furthermore, reposition therapy may be less effective in older infants who are increasingly more mobile and do not maintain a single sleeping position.

In 2003, the AAP issued a policy indicating that improvement in skull shape is usually seen in two (2) to three (3) months with exercise and repositioning of the infant. The AAP indicated that the use of skull-molding helmets seems to be beneficial primarily when there has been a lack of response to mechanical adjustments and exercises. However, the AAP noted further studies are needed to identify outcome with and without skull-molding helmets. Furthermore, the AAP did not report any functional impairment associated with plagiocephaly.

Pricing:

The HCPCS codes A8000, A8001, A8002, A8003, and A8004 describe protective helmets, hard or soft, either prefabricated or custom, including all accessories, components, and soft interface replacement **and do not specifically** describe CRO devices used for treatment of synostotic plagiocephaly OR non-synostotic plagiocephaly as described in this policy. HCPCS codes L0100 & L0110 were deleted 1/2007.

Generally, these codes are used for other medical or post-surgical treatments (such as for a protective helmet, not a remolding device orthosis) unrelated to plagiocephaly. If used, they are typically reimbursed at levels far below that suggested by the CRO manufacturers.

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