• COVERAGE:

As a non-surgical treatment of non-synostotic plagiocephaly, a CRO device is considered cosmetic and experimental or investigational. As an adjunctive postsurgical therapy for synostotic plagiocephaly, a CRO device is considered medically necessary.

NOTE: 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 deformities, trauma, tumors, infections, or disease may cause an abnormal structure. As an adjunctive postsurgical therapy for synostotic plagiocephaly, a CRO device, therefore, is allowed.

DESCRIPTION:

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

• premature birth,
• restrictive intrauterine environment,
• birth trauma,
• shortening of the sternocleidomastoid neck muscle (known as torticollis), and
• sleeping positions, or from the interaction of any of these conditions.

Infants with positional plagiocephaly may exhibit complex and multiple asymmetries affecting the cranial vault, skull base, and face.

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

The CRO device is customized to the patient's head shape. It is fabricated from a plaster of Paris impression 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 CRO device is known by several different names, such as:
CRANIAL REMOLDING ORTHOSIS (CRO) BAND
DME103.007
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

- DOC Band™ (Dynamic Orthotic Cranioplasty Band),
- STARband™ (Symmetry Through Active Remolding Band), or
- 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.

In addition, the available studies do not indicate whether positional plagiocephaly is associated with a functional impairment either at the time of diagnosis or during later childhood. The use of a CRO device would appear to be primarily for appearance and would be considered cosmetic in nature. Until additional studies become available to support one treatment technique as superior to another or as superior to no treatment, the use of a CRO device would appear to be investigational and/or cosmetic.

PRICING:

When coverage criteria are met, reimbursement requires submission of the orthotic invoice.

REFERENCES:

• Vles, J.S., "Helmet versus non-helmet treatment in nonsynostotic positional posterior plagiocephaly." Journal of Craniofacial Surgery
Cranial Remolding Orthosis (CRO) Band
DME103.007
Posted Date: 6/11/2003
Effective Date: 8/15/2003


Disclaimer:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.