Cranial Remolding Helmets

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

Cranial remolding helmets require precertification.

National Coverage Determination Policy	None
Local Coverage Determination Policy	None
Effective Date	05/30/11
Review/Revisions Date	01/2019, 10/18, 05/2018, 04/01/17, 02/01/16, 05/01/14
The Health Plan	Medicaid and Commercial plans will follow The Health Plan policy. Medicare plans will follow Medicare criteria and coding.

DESCRIPTION

Cranial orthosis has been researched as a noninvasive treatment of nonsynostotic skull deformities developing in infancy. It involves the use of a custom molded orthotic, either a helmet or a band that allows a deformed infant skull to self-correct during the period of most rapid head growth. The device exerts dynamic effect by compressing the skull prominences and permits more rapid growth expansion into flattened areas of a misshapen skull. Cranial orthosis has also been proposed as a postoperative adjunct for those undergoing surgery for synostotic skull deformity.

Positional plagiocephaly is treated conservatively and many cases do not require any treatment as the condition may resolve spontaneously when the infant begins to sit up. When the deformity is moderate or severe and a trial of repositioning the infant has failed, a pediatric neurologist, neurosurgeon, or

other appropriate specialist in craniofacial deformities may prescribe a cranial remodeling band to remodel the misshapen head. The custom molded orthotic is designed to fit a child's head for two to four months.

COVERAGE GUIDELINES

The Health Plan considers cranial remodeling bands (or helmets) as medically necessary orthoses for treatment of moderate to severe positional head deformities associated with premature birth, restrictive intrauterine positioning, cervical abnormalities, birth trauma, torticollis (shortening of the sternocleidomastoid muscle) and sleeping positions in children when banding is initiated at 4 to 12 months of age and the following conditions are met:

A two month trial of conservative therapy, consisting of repositioning the child's head such that the child lies opposite to the preferred position, has failed to improve the deformity and is judged to be unlikely to do so, and

One of the following must be met:

1. Anthropometric data (measurements used to evaluate abnormal head shape by measuring the distance in millimeters (mm) from one predesignated point on the face or skull to another, comparing the right and left sides) verifies that a moderate to severe plagiocephaly is documented by a physician experienced in such measurement.
    a. A difference of asymmetry greater than 6 mm between anthropometric measurements warrants coverage of a trial of orthotic banding to correct the craniofacial deformity.
    b. For brachycephaly evaluation, a cephalic index or two standard deviations below mean (head narrow for its length) or two standard deviations above mean (head wide for its length) warrants coverage of a trial of orthotic banding to correct the craniofacial deformity in a child after 4 months of age and before 12 months of age.

    The most significant measurements used in this initial evaluation are skull base asymmetry, cranial vault asymmetry, orbitotragial depth, and cephalic index.

    Note: These measurements are generally obtained by the orthotist fitting the band or helmet.
2. Premature infants with dolichocephalic head shape who have developed a misshapen head secondary to sustained head position.
3. Infants who develop significant plagiocephaly secondary to a constant head position required for long-term hyperalimentation who do not respond to simple changing of the catheter location allowing the head to be repositioned.
4. Members with moderate to severe residual plagiocephaly after surgical correction.
5. Members with excess frontal bossing secondary to sagittal synostosis.

A second cranial remodeling band or helmet is considered medically necessary for children who meet the aforementioned criteria, if the asymmetry has not resolved after two to four months.

The Health Plan considers the use of a cranial remodeling band (or helmet) cosmetic for persons not meeting the above criteria.

The Health Plan considers use of a cranial remodeling band (or helmet) medically necessary for infants with synostotic plagiocephaly to correct continued asymmetry following surgery when criteria in Section

I above are met. The Health Plan considers the use of a cranial remodeling band (or helmet) without surgery to correct asymmetry in infants with synostotic plagiocephaly as cosmetic.

While infants with positional plagiocephaly may be treated with head positioning and/or helmeting, the standard treatment for synostotic plagiocephaly (asymmetrical head caused by premature closure of the cranial sutures) is surgery. There is some evidence suggesting that a cranial remodeling band (or helmet) may improve outcomes following surgery to treat synostotic plagiocephaly.

Examples of brands of cranial remodeling bands and helmets include the DOC BAND®, Gillette Children's Craniocap™, and the STARband™ Cranial Headband. Average treatment time with the cranial remodeling band or helmet is four and a half months.

REPAIR, REPLACEMENT, AND REASONABLE USEFUL LIFETIME

Repair will be reviewed on a case by case basis.

Replacements will be reviewed on a case –by-case basis

CODING INFORMATION

HCPCS codes: Codes covered if selection criteria are met.

HCPCS CODES

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 remolding orthotic, pediatric, rigid, with soft interface material, custom fabricated, included fitting, and adjustment Covered for MHT member. Will cover for Commercial member's ages 2 years old or younger. Medicare product lines are to use the "L" code.

ICD-10 codes: Codes covered if selection criteria are met.

ICD-10 CODES

M43.6	Torticollis, unspecified
M95.2	Other specified deformity of head
Q67.0-Q67.4	Certain congenital musculoskeletal deformities of skull, face, and jaw (plagiocephaly)
Q68.0	Certain congenital musculoskeletal anomalies of sternocleidomastoid muscle
Q75.0-Q75.2,Q75.9	Other congenital musculoskeletal anomalies of skull and face bones (craniosynostosis)

P15.0-P15.3,P15.5,P15.8	Other specified birth trauma

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
    a. Member's name
    b. Date
    c. Description of item. The medical record must contain the information that supports the request for each item and must be submitted with the precertification if the item requires precertification, or with the claim, if no precertification was required
    d. Order must include diagnosis code
    e. Physician signature with date. Date stamps are not appropriate
    f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

       The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.
3. Proof of delivery to be kept on file by the provider of the item.

   Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

   Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

Precertification is required when supplies used are greater than the usual maximum quantity listed in above. There must be adequate, clear documentation in the medical record corroborating the medical necessity of this amount. This documentation is to be submitted with precertification.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item is met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier, if they have not obtained a valid ABN.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. dmepdac.com/

DEFINITIONS AND DESCRIPTIONS

Plagiocephaly: The head can become flattened at one side, causing the head to look asymmetrical and distorted (e.g., the ears are not aligned).

Brachycephaly: The whole back of the head can become flattened, causing a widening of the head. In some cases, the front of the skull may bulge out in compensation.

Plagiocephaly/Brachycephaly: An asymmetrical head shape, sometimes referred to as "flat head syndrome," is most often the result of an infant spending extended period 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 synostotic (premature union of cranial sutures).

Dolichocephalic: Having a head much longer than it is broad, especially one with a cephalic index under 75.

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indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

INTERNET LINKS AND SOURCES

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The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11