Medical Coverage Policy | Cranial Orthoses (Adjustable) for Positional Plagiocephaly and Craniosynostoses

EFFECTIVE DATE:02|03|2015
POLICY LAST UPDATED: 05/18/2022

OVERVIEW
Cranial orthoses involve an adjustable helmet or band that progressively molds the shape of the infant cranium by applying corrective forces to prominences while leaving room for growth in the adjacent flattened areas. A cranial orthotic device may be used to treat postsurgical synostosis or positional plagiocephaly in pediatric patients.

PRIOR AUTHORIZATION
Prior authorization review is not required.

POLICY STATEMENT
Medicare Advantage Plans and Commercial
Use of an adjustable cranial orthosis may be considered medically necessary following cranial vault remodeling surgery for synostosis and treatment of persistent plagiocephaly or brachycephaly without synostosis

Use of an adjustable cranial orthosis for synostosis in the absence of cranial vault remodeling surgery is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

For all other indications not outlined above, the use of an adjustable cranial orthosis is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

MEDICAL CRITERIA
Not applicable

BACKGROUND
Craniosynostoses
An asymmetrically shaped head may be synostotic or nonsynostotic. Synostosis, defined as premature closure of the sutures of the cranium, may result in functional deficits secondary to increasing intracranial pressure in an abnormally or asymmetrically shaped cranium. The type and degree of craniofacial deformity depends on the type of synostosis. The most common is scaphocephaly, a narrowed and elongated head resulting from synostosis of the sagittal suture. Trigonocephaly, in contrast, is premature fusion of the metopic suture and results in a triangular shape of the forehead. Unilateral synostosis of the coronal suture results in an asymmetric distortion of the forehead called plagiocephaly, and fusion of both coronal sutures results in brachycephaly. Combinations of these deformities may also occur.

Treatment
Synostotic deformities associated with functional deficits are addressed by surgical remodeling of the cranial vault. The remodeling (reshaping) is accomplished by opening and expanding the abnormally fused bone. In a review of the treatment of craniosynostosis, Persing (2008) indicated that premature fusion of one or more cranial vault sutures occurs in approximately 1 in 2500 births. Of these craniosynostoses, asymmetric deformities involving the cranial vault and base (eg, unilateral coronal synostosis) will have a higher rate of postoperative deformity, which would require additional surgical treatment. Persing suggested that use of cranial orthoses postoperatively may serve 2 functions: (1) they protect the brain in areas of large bony

defects, and (2) they may remodel the asymmetries in skull shape, particularly when the bone segments are more mobile.

For individuals who have open or endoscopic surgery for craniosynostosis who receive a postoperative cranial orthosis, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Overall, the evidence on the efficacy of cranial orthoses following endoscopic-assisted or open cranial vault remodeling surgery for craniosynostosis is limited. However, functional impairments are related to craniosynostosis, and there is a risk of harm from additional surgery when severe deformity has not been corrected. Because cranial orthoses can facilitate remodeling, use of a cranial orthosis is likely to improve outcomes after cranial vault remodeling for synostosis. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Plagiocephaly

Plagiocephaly without synostosis, also called positional or deformational plagiocephaly, can be secondary to various environmental factors including, but not limited to, premature birth, restrictive intrauterine environment, birth trauma, torticollis, cervical anomalies, and sleeping position. Positional plagiocephaly typically consists of right or left occipital flattening with advancement of the ipsilateral ear and ipsilateral frontal bone protrusion, resulting in visible facial asymmetry. Occipital flattening may be self-perpetuating in that once it occurs, it may be increasingly difficult for the infant to turn and sleep on the other side. Bottle feeding, a low proportion of "tummy time" while awake, multiple gestations, and slow achievement of motor milestones may contribute to positional plagiocephaly. The incidence of plagiocephaly has increased rapidly in recent years; this is believed to be a result of the "Back to Sleep" campaign recommended by the American Academy of Pediatrics, in which a supine sleeping position is recommended to reduce the risk of sudden infant death syndrome. It has been suggested that increasing awareness of identified risk factors and early implementation of good practices will reduce the development of deformational plagiocephaly.

Treatment

It is estimated that about two-thirds of plagiocephaly cases may auto-correct spontaneously after regular changes in sleeping position or following physical therapy aimed at correcting neck muscle imbalance. A cranial orthotic device is usually requested after a trial of repositioning fails to correct the asymmetry, or if the child is too immobile for repositioning.

Cranial Orthoses for Positional Plagiocephaly

Results from the HElmet therapy Assessment in Deformed Skulls trial have suggested that, in a practice setting, the effectiveness of cranial orthoses may not differ from the natural course of development for infants with moderate to severe plagiocephaly and brachycephaly. However, the validity of these results is limited by the low percentage of infants who wore the cranial orthoses for the duration of the trial and the relatively low percentage of infants who achieved recovery in either group. In addition, the efficacy of cranial orthoses in infants with very severe plagiocephaly was not addressed. A few reports have assessed the association between positional plagiocephaly and functional impairments. The largest controlled study found no difference in function between infants with plagiocephaly and age-matched concurrent controls. While some series have suggested an association between plagiocephaly and developmental delay, they lacked controls and did not evaluate the possible causal relation to observed association. Results of a study on right-sided verses left-sided plagiocephaly suggested an association between left-sided and functional performance but these results have not been confirmed. During the 2019 update for this policy, professional society clinical input was sought with a response that acknowledged the evidence limitations but an endorsement of current professional guidelines.

Regulatory Status

Several devices cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process are intended to apply passive pressure to prominent regions of an infant's cranium to improve cranial

symmetry and/or shape in infants from 3 to 18 months of age. Food and Drug Administration product code: MVA.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable durable medical equipment benefits/coverage.

CODING

Medicare Advantage Plans and Commercial

The following HCPCS code(s) is medically necessary when filed with a covered diagnosis:

S1040 Cranial remolding orthosis, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s).

Covered ICD-10 Diagnoses

Q67.3
Q75.0

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, July 2022
Provider Update, December 2021
Provider Update, November 2020
Provider Update July 2019
Provider Update, December 2017

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