Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP125

Section: Medical Benefit Policy

Subject: Cranial Remodeling Orthotic

I. Policy: Cranial Remodeling Orthotic

II. Purpose/Objective:

To provide a policy of coverage regarding Cranial Remodeling Orthotic

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

Plagiocephaly: an asymmetrically shaped head**.**

Non-synostotic plagiocephaly: also called positional plagiocephaly can be secondary to various environmental factors including, but not limited to, premature birth, restrictive intrauterine environment, birth trauma, and sleeping position.

DESCRIPTION:
Cranial remodeling orthotic devices are intended to apply pressure to prominent regions of the cranium in order to improve cranial symmetry in infants with moderate to severe non-synostotic positional plagiocephaly.

INDICATIONS:
Cranial remodeling orthotics may be considered medically necessary in infants less than eighteen (18) months of age who:

- Are diagnosed with synostotic plagiocephaly and the orthotic is being used during the post-surgical period; **or**
- are diagnosed with non-synostotic positional plagiocephaly; **and**
    - have not responded to a two-month trial of repositioning **or**;
    - a 2-month trial of physical therapy if appropriate because of clinical condition (e.g. congenital torticollis); **and**
    - are considered unlikely to respond to continued repositioning or physical therapy due to the severity of the deformity (generally 2 standard deviations or more above or below the mean cranial index for age and gender). Note: Cranial Index (CI) is defined as the ratio of the width ÷ length x 100. A CI ranging from 76-90% is considered normocephalic.

LIMITATIONS:
Coverage is subject to any conditions or limitations as may be described in the applicable benefit documents.

EXCLUSIONS:
There is insufficient evidence to support the efficacy of cranial remodeling orthotic use in children older than 18 months of age and is therefore **NOT COVERED**.

Cranial orthotic devices are not intended for use in infants with head deformities due to uncorrected craniosynostosis or hydrocephalus and is therefore **NOT COVERED**.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

CODING ASSOCIATED WITH: Cranial Remodeling Orthotic
The coding listed in this document may not represent the comprehensive range of codes that may be associated with this service.

A8000 Helmet, protective, soft, prefabricated, includes all components and accessories

A8001 Helmet, protective, hard, prefabricated, includes all components and accessories

A8002 Helmet, protective, soft, custom fabricated, includes all components and accessories

A8003 Helmet, protective, hard, custom fabricated, includes all components and accessories

A8004 Soft interface for helmet, replacement only

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 orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Winifred S. Hayes, Hayes Inc. Online, Cranial Orthotic Devices, March 5, 2004.

Biggs WS. Diagnosis and management of positional head deformity. American Family Physician, May 2003;67(9):1953-1956.

Persing J, James H, et. al., American Academy of Pediatrics Clinical Report, Prevention and Management of Positional Skull Deformities in Infants, Pediatrics 112(1):199-202, July 2003.

ECRI, HTAIS Database, Windows on Medical Technology, Cranial Orthosis for the Treatment of Deformational Plagiocephaly in Infants: 2003 Update. Issue No.113. Dec. 2003.

Pollack IF, Losken HW, Fasick P, Diagnosis and Management of Posterior Plagiocephaly, Pediatrics 99(2): 180-185. Feb 1997.

Loveday BPT, de Chalain TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? Journal of Craniofacial Surgery July 2001;12(4):308-313.

Institute for Clinical Systems Improvement. Technical Assessment Report. Cranial Orthoses for Deformational Plagiocephaly

Lee WT, Richards K, Redhed J,Papay FA. A pneumatic orthotic cranial molding helmet for correcting positional plagiocephaly. J Craniofac Surg 2006 Jan;17(1):139-44.

Graham JM, Gomex M, Halberg A, Earl DL, Kreutzman JT, Cui J, Guo X. Management of deformational plagiocephaly: repositioning versus orthotic therapy. J Pediatr 2005;146:258-62.

American Academy of Neurological Surgeons (AANS). Craniosynostosis and craniofacial disorders. [AANS Website]. 2019. https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Craniosynostosis-and-Craniofacial-Disorders

Ridgway EB, Berry-Candelario J, Grondin RT, et al. The management of sagittal synostosis using endoscopic suturectomy and postoperative helmet therapy. J Neurosurg Pediatr. 2011; 7(6):620-626

Couture DE, Crantford JC, Somasundaram A, et al. Efficacy of passive helmet therapy for deformational plagiocephaly: report of 1050 cases. Neurosurg Focus. 2013; 35(4):E4.

van Wijk RM, van Vlimmeren LA, Groothuis-Oudshoorn CG, et al. Helmet therapy in infants with positional skull deformation: Randomised controlled trial. BMJ. 2014 May 1;348:g2741.

Goh JL, Bauer DF, Durham SR, Stotland MA. Orthotic (helmet) therapy in the treatment of plagiocephaly Neurosurg Focus. 2013 Oct;35(4).

Buchanan EP, Hollier LH, Jr. Overview of craniosynostosis. UpToDate. Reviewed February 2015.

Mundinger GS, Rehim SA, Johnson O, et al. Distraction osteogenesis for surgical treatment of craniosynostosis: A systematic review. Plast Reconstr Surg. 2016;138(3):657-669.

Utria AF, Lopez J, Cho RS, et al. Timing of cranial vault remodeling in nonsyndromic craniosynostosis: A single-institution 30-year experience. J Neurosurg Pediatr. 2016;18(5):629-634

Lam S, Pan IW, Strickland BA, et al. Factors influencing outcomes of the treatment of positional plagiocephaly in infants: a 7-year experience. J Neurosurg Pediatr. 2017 Mar;19(3):273-281.

Radiopaedia, Cephalic Index. https://radiopaedia.org/articles/cephalic-index?lang=us

Kelly, K. M., Joganic, E. F., Beals, S. P., Riggs, J. A., McGuire, M. K., & Littlefield, T. R. Helmet Treatment of Infants With Deformational Brachycephaly. 2018 Global Pediatric Health.

Ballardini E, Sisti M, Basaglia N, Benedetto M, Baldan A, Borgna-Pignatti C, Garani G. Prevalence and characteristics of positional plagiocephaly in healthy full-term infants at 8-12 weeks of life. Eur J Pediatr. 2018 Oct;177(10):1547-1554

Cognitive Outcomes and Positional Plagiocephaly. Collett BR, Wallace ER, Kartin D, Cunningham ML, Speltz ML. Pediatrics. 2019 Jan 11. pii: e20182373.

Picart T, Beuriat PA, Szathmari A, et al. Positional cranial deformation in children: A plea for the efficacy of the cranial helmet in children. Neurochirurgie. 2020; 66(2):102-10

Wen, J., Qian, J., et al. Effect of helmet therapy in the treatment of positional head deformity. J Paediatr Child Health. 2020 Dec 23

Jung BK, Yun IS. Diagnosis and treatment of positional plagiocephaly. Arch Craniofac Surg. 2020 Apr;21(2):80-86

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/05

Revised: 6/06 (references); 6/07, 7/16 (added indication), 6/19 (added cephalic index criteria per DHS), 6/22 (clarified exclusions)

Reviewed: 6/08, 6/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 6/17, 6/18, 6/20, 6/21, 6/23, 6/24

CMS UM Oversight Committee Approval: 12/23, 7/24