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 use in children older than 18 months of age.

Cranial orthotic devices are not intended for use in infants with head deformities due to uncorrected craniosynostosis or hydrocephalus.

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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.
REFERENCES:
Radiopaedia, Cephalic Index. https://radiopaedia.org/articles/cephalic-index?lang=us

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)
Reviewed: 6/08, 6/09, 7/10, 7/11, 7/12, 7/13, 7/14, 7/15, 6/17, 6/18, 6/20
Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.