

Medical Policy



Cranial Orthosis and Protective Helmets

Description

A cranial orthosis helmet (S1040) is primarily used to correct a positional deformity (plagiocephaly) of the skull in infants. It is also used to continue remolding of the skull following surgical correction of premature fusion of the sutures of the skull (cranial synostosis).

Cranial orthotic devices (helmets) (S1040), if fitted properly and able to enlarge with an infant's growth, are safe and effective for the treatment of plagiocephaly (an asymmetrically shaped head).

Policy

A cranial orthosis helmet (S1040) is considered **reasonable and necessary** for Members that meet coverage criteria.

Policy Guidelines

Coverage Criteria:

1. Must be ordered by the Member's treating physician; and
2. A cranial orthosis for severe non-synostotic plagiocephaly may be considered as a treatment for the following candidates:
 - a) Infants 3-12 months of age who have failed conservative treatment (i.e., physical therapy for torticollis and/or positional changes).
 - b) If the child is between 12 and 18 months of age, the case will be reviewed on an individual consideration basis.
3. For synostotic plagiocephaly a cranial orthosis following corrective surgery.
4. The cranial orthosis must be an FDA-approved device intended for the treatment of deformational plagiocephaly (including plagiocephalic, brachycephalic and scaphocephalic shaped heads) in order to provide a reasonable assurance of safety and effectiveness

Protective helmets (A8000-A8004) are considered **not** reasonable and necessary since they are safety equipment and are of benefit even in the absence of illness or injury.

Medical Policy



Cranial Orthosis and Protective Helmets

Exclusions:

- Cranial orthosis prescribed for the initial treatment of cranial synostosis
- The costs of fitting and adjustments are included in the cost of the orthosis and cannot be billed separately
- Cranial orthosis used for Members 19 months or older or younger than 3 months

HCPCS Level II Codes and Description

| | |
|-------|---|
| S1040 | Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s) |
| A8000 | Helmet, protective, soft, prefabricated, includes all components and accessories |
| A8001 | Helmet, protective, hard, prefabricated, includes all components and accessories |
| A8002 | Helmet, protective, hard, 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 |

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit

Medical Policy



Cranial Orthosis and Protective Helmets

determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

References

1. Balan P, Kushnerenko E, Sahlin P, Huotilainen M, Naatanen R, Hukki J. Auditory ERPs Reveal Brain Dysfunction in Infants with Plagiocephaly. *J Craniofacial Surg.* 2002; 13:520-525.
2. Gupta PC, Foster J, Crowe S, Papay FA, Luciano M, Traboulsi EI. Ophthalmologic Findings in Patients with Nonsyndromic Plagiocephaly. *J Craniofacial Surg.* 2003; 14:529-532.
3. Loveday BP, de Chalain TB. Active Counterpositioning or Orthotic Device to Treat Positional Plagiocephaly? *J Craniofacial Surg.* 2001; 12:308-313.
4. Moss SD. Nonsurgical, nonorthotic treatment of occipital plagiocephaly: What is the natural history of the misshapen neonatal head? *J Neurosurg.* 1997; 87:667-70.
5. Mulliken JB, Woude DLVander, Hansen M, LaBrie RA, Scott RM. Analysis of Posterior Plagiocephaly: Deformational versus Synostotic. *Plastic Reconstructive Surg.* 1999; 103:371-380.
6. Panchal J, Amirshaybani H, Gurwitch R, et al. Neurodevelopment in Children with Single-Suture Craniosynostosis and Plagiocephaly without Synostosis. *Plastic Reconstructive Surg.* 2001; 108:1492-1498.

Medical Policy



Cranial Orthosis and Protective Helmets

7. Pattisapu JV, Walker ML, Myers GG, Cheever J. Concepts of Pediatric Neurosurgery: Use of Helmets for Positional Molding. Salt Lake City, Utah: Basel, Karger 1989; 9:178-184.
8. Persing J, James H, Swanson J, et al. Prevention and management of positional skull deformities in infants. The American Academy of Pediatrics. Clinical report. Guidance for the clinician in rendering pediatric care. Pediatrics. 2003; 112:199-202.
9. Ripley CE, Pomatto J, Beals SP, Joganic EF, Manwaring KH, Moss SD. Treatment of Positional Plagiocephaly with Dynamic Orthotic Cranioplasty. J Craniofacial Surg. 1994; 5:150-159.
10. Teichgraeber JF, Ault JK, Baumgartner J, et al. Deformational Posterior Plagiocephaly: Diagnosis and Treatment. Cleft Palate-Craniofacial J. 2002; 39:582-586.
11. UnitedHealthcare Policy CS095.H Accessed 11/25/19.
<https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medicaid-comm-plan/plagiocephaly-craniosynostosis-treatment-cs.pdf>

Applicable URAC Standard

| | |
|--------|-------------------------------------|
| Core 8 | Staff operational tools and support |
|--------|-------------------------------------|

Change/Authorization History

| Revision Number | Date | Description of Change | Prepared / Reviewed by | Approved by | Review Date: | Effective Date: |
|-----------------|----------|--|------------------------|-------------|--------------|-----------------|
| A | 11-20-06 | Initial Release | Rosanne Brugnani | Ken Fasse | n/a | |
| 01 | | Annual Review – no changes | Susan Glomb | Ken Fasse | 12-2008 | |
| 02 | 12-22-09 | Annual Review-No changes | Susan Glomb | Ken Fasse | Dec.2009 | |
| 03 | 11-24-10 | Annual Review- policy updated to reflect | Susan Glomb | Ken Fasse | Nov.2010 | |

Medical Policy



Cranial Orthosis and Protective Helmets

| | | | | | | |
|----|----------|--|-------------|----------------|---------------|--|
| | | BCBSM policy criteria. | | | | |
| 04 | 12-04-10 | Annual Review- no additional changes. | Susan Glomb | Ken Fasse | | |
| 05 | 5-3-11 | Policy changed to include coverage of A8000-A8004 for BMCHP members. | Susan Glomb | Dr. Almasri | | |
| 06 | 07-20-11 | Added Important Note to all Medical Policies | Susan Glomb | Dr. B. Almasri | | |
| 07 | 11-08-11 | Annual Review. Added References to Policy | Susan Glomb | Dr. B. Almasri | Nov. 2011 | |
| 08 | 1-10-12 | Added language regarding protective helmet (A8000 – A8004) exclusion. | Susan Glomb | Dr. B. Almasri | Jan. 2012 | |
| 09 | 11-28-12 | Annual Review – No changes | Susan Glomb | Dr. B. Almasri | Nov 12 | |
| 10 | 12-18-13 | Annual review. No changes | Susan Glomb | Dr. B. Almasri | Dec. 13 | |
| 11 | 11-24-14 | Annual Review. No changes | Susan Glomb | Dr. B. Almasri | | |
| 12 | 12-15-15 | Annual review. No changes | Susan Glomb | Dr. B. Almasri | 12-15--15 | |
| 13 | 12-05-16 | Annual Review. No Changes. | Lisa Wojno | Dr. B. Almasri | December 2016 | |
| 14 | 02-15-17 | Policy updated to state in the Coverage area under b. If the child is between 12 and 18 months of age, the case will be reviewed on an individual consideration basis. | Susan Glomb | Dr. B. Almasri | Feb 2017 | |

Medical Policy



Cranial Orthosis and Protective Helmets

| | | | | | | |
|----|----------|---|--------------|--------------------|---------------|----------|
| 15 | 12-15-17 | Annual Review. No Changes. | Lisa Wojno | Dr. Cheryl Lerchin | December 2017 | |
| 16 | 12-01-18 | Annual Review. No Changes. | Lisa Wojno | Dr. C. Lerchin | December 2018 | |
| 17 | 11-25-19 | Annual Review. Added new reference to policy. | Carol Dimech | Dr. C. Lerchin | November 2019 | 11-25-19 |