

Medical Policy



Cranial Orthosis and Protective Helmets

Description

A cranial orthosis helmet (S1040) is primarily used to correct a positional deformity (plagiocephaly) or for a non-synostotic (non-fusion) deformation of the skull in infants. It is also used to continue remodeling 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 practitioner; 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 (i.e., a trial of conservative therapy is not needed when the cranial remodeling band is used following surgery) may be medically necessary.
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.

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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
- The use of a cranial remodeling band or helmet is considered experimental and investigational for Calcified Cephalohematoma.

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.

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The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit 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 practitioner in connection with diagnosis and treatment decisions.

Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References

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3. Loveday BP, de Chalain TB. Active Counterpositioning or Orthotic Device to Treat Positional Plagiocephaly? *J Craniofacial Surg.* 2001; 12:308-313.
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13. BCBSM, Cranial Orthosis (Helmet or Band Therapy) as a Treatment of Plagiocephaly
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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 Brugnoni	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 BCBSM policy criteria.	Susan Glomb	Ken Fasse	Nov.2010	
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	

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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	
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
18	11-11-20	Annual Review. Added new reference to policy. Per CMS, replaced physician with practitioner.	Carol Dimech	Dr. C. Lerchin	November 11, 2020	November 11, 2020
19	11-02-21	Annual Review. Aetna update to include use of a Cranio Remodeling band or helmet is considered experimental and investigational for Calcified Cephalohematoma. Added NCD/LCD verbiage to "Important Note".	Carol Dimech/Susan Glomb	Dr. C. Lerchin	11-02-21	11-2-21
20	11-17-22	Annual review. Added new reference.	Carol Dimech	Dr. C. Lerchin	11-17-22	11-17-22
21	11-8-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	11-8-23	11-8-23