Medical Policy

Northwood

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 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

For WellSense Mass Health, Mass Health Care Plus, ACO and Health New England Medicaid see Mass Health Guidelines box below.

Coverage Criteria:

1. Must be ordered by the Member's treating practitioner; and
2. A cranial orthosis for **moderate to severe** non-synostotic plagiocephaly may be considered as a treatment for the following candidates:
    - Infants 3-12 months of age who have failed conservative treatment (i.e., physical therapy for torticollis and/or positional changes).
    - If the child is over 12 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 are reasonable and necessary for Medicaid members with a diagnosis of ataxia (gait disturbance), seizure disorder, or safety risk issues.

Cranial Orthosis and Protective Helmets

- 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

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

Cranial Orthosis and Protective Helmets

Northwood follows Mass Health Guidelines for Mass Health, Mass Health Care Plus, WellSense ACO's and Health New England Medicaid to determine medical necessity for Cranial Orthoses.

MASS HEALTH GUIDELINES FOR CRANIAL ORTHOSES

Clinical Coverage MassHealth bases its determination of medical necessity for cranial orthoses on a combination of clinical data and the presence of indicators that would affect the relative risks and benefits of the product. The required showing differs depending on whether the cranial orthosis is required for postsurgical treatment of a craniosynostotic deformity or whether it is required for treatment of nonsynostotic PCD. These clinical data and indicators include, but are not limited to, the following:

1. Synostotic deformities A cranial orthotic may be medically necessary for treatment of synostotic deformities when a pediatric neurosurgeon or craniofacial surgeon has documented the need for surgical correction of craniosynostosis, and the postoperative need for a cranial orthotic.

2. Nonsynostotic PCD A cranial orthotic may be medically necessary for treatment of nonsynostotic PCD when all of the following criteria (a, b, and c) are met

a. A pediatric neurosurgeon or craniofacial surgeon has determined that the member does not have craniosynostosis;

b. A pediatric neurosurgeon or craniofacial surgeon has determined that the member has a severe skull deformity that, unless corrected by a cranial orthotic, is likely to result in significant, permanent deformity;

c. Clinical documentation demonstrates that flattening persists despite a two-month period of positional therapy and presence of the characteristics below. Note: a trial of positional therapy is not required if the child is older than six months, or has a co-morbid diagnosis or delay in diagnosis that prevents completion of a trial of conservative therapy.

i. A trial of positional therapy began between the ages of two to six months, included extended periods of "tummy time," posturing the infant with foam wedges, keeping objects of interest to the side opposite the posterior cranial

flattening, and regular alternation of feeding sides and positions for nursing or bottle-feeding; and

ii. ii. The trial therapy has failed to improve the deformity and is judged to be unlikely to do so; and

iii. iii. Cranial vault anthropometric measurements show at least one of the following (1, 2, or 3): 1) Asymmetry discrepancy of 10 mm or more in one of the following anthropometric measures: cranial vault, skull base, or orbitotragal depth

2) Cranial Vault Asymmetry Index (CVAI) of >8.75 , where the CVAI is the absolute value of the difference between the measurements of two head diagonals 30 degrees apart divided by the length of the smaller diagonal then multiplied by 100:

a) <3.5 No treatment

b) 3.5 – 6.25 Repositioning program

c) 6.25-8.75 Repositioning program

d) >8.75 Repositioning program and orthotic treatment

3) A cephalic index (CI), head width times 100 divided by head length, of two or more standard deviations above or below the mean for age and gender.

Sex	Age	-2 SD	-1 SD	Mean	+1 SD	+2 SD
Male	16 days to 6 months	63.7	68.7	73.7	78.7	83.7
	6 to 12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days to 6 months	63.9	68.6	73.3	78.0	82.7
	6 to 12 months	69.5	74.0	78.5	83.0	87.5

iv.

Noncoverage: MassHealth does not consider cranial orthoses to be medically necessary under circumstances that include, but are not limited to, the following:

1. Cranial orthoses are not medically necessary for skull deformities that are not likely to cause permanent deformity;

2. Cranial orthoses are not medically necessary if they are instituted when head growth has stabilized, generally around 18 months.

3. Cranial orthoses are cosmetic in nature and not medically necessary in infants with mild to moderate plagiocephaly;

4. Cranial orthoses are contraindicated in infants with hydrocephalus; and

5. More than two cranial orthoses are considered not medically necessary when estimates of time to outgrow two devices exceed the maximum required time to treat.

Section III: Submitting Clinical Documentation Requests for PA for cranial orthoses must be submitted by an orthotics provider and accompanied by clinical documentation that supports the medical necessity for this product. In some cases, photographic documentation of facial, orbital, and auricular involvement may also be necessary, including frontal, lateral, and vertex images.

A. Documentation of medical necessity for a cranial orthosis for postsurgical treatment of a synostotic deformity must include all of the following: 1. Clinical documentation by the member's pediatric neurosurgeon or craniofacial surgeon of a diagnosis of craniosynostosis; 2. Clinical documentation by the member's pediatric neurosurgeon or craniofacial surgeon of the need for surgical correction of craniosynostosis and the postoperative need for the cranial orthosis; and 3. A written prescription by the member's pediatric neurosurgeon or craniofacial surgeon for the cranial orthosis.

B. Documentation of medical necessity for a cranial orthosis for treatment of non-synostotic PCD must include all of the following:

1. A written prescription by the member's pediatric neurosurgeon or

craniofacial surgeon for the cranial orthosis;

2. A written determination by the member's pediatric neurosurgeon or craniofacial surgeon that the member does not have craniosynostosis;

3. Anthropometric assessment by the orthotics provider of cranial shape and measurements taken for determining cranial vault asymmetry (CVA), cranial vault asymmetry index (CVAI), and

transcranial measurements of the cephalic index (CI) provided by the orthotic provider; and

4. For children less than six months old, documentation that medical personnel have instructed caregivers in appropriate positional therapies and that those therapies have been administered for at least two months without improvement; or documentation of a comorbid diagnosis or delay in diagnosis that prevents completion of a trial of conservative therapy.

C. All cranial orthoses require prior authorization.

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

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. Opthalmologic 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, Amirsheybani H, Gurwitch R, et al. Neurodevelopment in Children with Single-Suture Craniosynostosis and Plagiocephaly without Synostostosis. Plastic Reconstructive Surg. 2001; 108:1492-1498.

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 *https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medicaid-comm-plan/plagiocephaly-craniosynostosis-treatment-cs.pdf* Last accessed and reviewed 11-13-25.

12. Aetna Policy CPB 0379: Cranial Remodeling., *https://www.aetna.com/cpb/medical/data/300_399/0379.html* Last accessed/reviewed 11/13/25.

13. BCBSM, Cranial Orthosis (Helmet or Band Therapy) as a Treatment of Plagiocephaly *https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/76790.pdf* Last accessed and reviewed 11/13/25.

14. Guidelines for Medical Necessity Determination for Cranial Orthosis. (*https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-cranial-*

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orthoses#:~:text=Cranial%20orthoses%20are%20used%20in,brachycephaly%2C%20and%20positional%20nonsynostotic%20plagiocephaly Accessed/reviewed 11-13-2025

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	11-28-12	Annual review – no changes.	Susan Glomb	Dr. B. Almasri	Nov. 2012	
09	12-18-13	Annual review. No changes	Susan Glomb	Dr. B. Almasri		
10	11-25-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
11	12-15-15	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
12	12-05-16	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016	

13	12-15-17	Annual Review. No Changes.	Lisa Wojno	Dr. Cheryl Lerchin	December 2017	
14	12-01-18	Annual Review. No Changes.	Lisa Wojno	Dr. C. Lerchin	December 2018	
15	11-25-19	Annual Review. Added new reference to policy.	Carol Dimech	Dr. C. Lerchin	November 2019	11-25-19
16	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
17	11-02-21	Annual Review. Aetna update to include the use of a cranial remodeling band or helmet is considered experimental and investigational for Calcified Cephalohematoma.	Carol Dimech/Susan Glomb	Dr. C. Lerchin	November 2, 2021	
18	11-8-21	Added NCD, LCD verbiage to "Important Note".	Carol Dimech	Dr. C. Lerchin	November 8, 2021	
19	11-17-22	Annual review. Added new reference.	Carol Dimech	Dr. C. Lerchin	11-17-22	11-17-22
20	11-8-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	11-8-23	11-8-23
21	11-11-24	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	11-11-24	11-11-24
22	12-30-24	Updated policy to identify diagnoses to include moderate to severe conditions.	Susan Glomb/Carol Dimech	Dr. C. Lerchin	12-30-24	12-30-24
23	4-21-25	Policy updated to include Mass Health guidelines for Cranial Orthosis and	Susan Glomb	Lisa Wojno	April 2025	4-21-25

		Protective Helmets. Individual box added.				
24	11-13-25	Annual review. No changes.	Lisa Wojno	Dr. C. Lerchin	11-13-25	11-13-25