



Guidelines for Medical Necessity Determination for Cranial Orthoses

This edition of Guidelines for Medical Necessity Determination (Guidelines) identifies the clinical information MassHealth needs to determine medical necessity for cranial orthoses. Cranial orthoses are used in the treatment of postsurgical cranial molding, brachycephaly, and positional nonsynostotic plagiocephaly. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

These guidelines apply to comprehensive services for the preparation, fitting, and subsequent adjustment of cranial orthoses. Providers should consult MassHealth regulations at [130 CMR 442.000](#) (orthotics services) and [450.000](#) (administrative and billing regulations), The Orthotics and Prosthetic Payment and Coverage Guidelines Tool, and [Subchapter 6 of the Orthotics Manual](#) for information about coverage, limitations, service conditions, and other prior authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care Organization, Senior Care Organization (SCO), or a Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

SECTION I. GENERAL INFORMATION

1

Historically torticollis and intrauterine events have been the principal causes of plagiocephaly. However, since the 1992 American Academy of Pediatrics' recommendation to place babies on their backs to sleep in order to prevent sudden infant death syndrome (SIDS), there has been an increase in diagnoses of brachycephaly and positional nonsynostotic plagiocephaly. Brachycephaly is a uniform flattening of the posterior aspect of the head. Positional nonsynostotic plagiocephaly, also called deformational plagiocephaly or positional cranial deformity (PCD), results from external pressure (molding) that causes the skull to become misshapen. It is characterized by unilateral occipital flattening that is often accompanied by ipsilateral advancement of the ear and frontal region, along with orbital asymmetry. Positional skull deformities are treated conservatively and, in many cases, do not require any specific treatment, as the condition may resolve spontaneously when the infant begins to roll over and, later, to sit up.

In 2011, the American Academy of Pediatrics published a report on the prevention and management of positional skull deformities in infants. The report recommends positional therapies for mild to moderate skull deformities and cranial orthoses for severe positional deformities. Cranial orthotic therapy is diminished in efficacy if instituted when head growth has stabilized, generally around age one year. Individual cases and postsurgical treatment may vary.

Craniosynostosis is a nonpositional cause of abnormal head shape in infants and occurs when one or more of the sutures in the infant's skull fuse prematurely. The premature fusion of one or more sutures

exerts pressure on the other skull bones to expand out of proportion, leading to abnormal skull shape. Craniosynostosis is treated with surgery.

MassHealth considers approval for coverage of cranial orthoses on an individual, case-by-case basis, in accordance with 130 CMR 450.204 and 130 CMR 442.000.

2

SECTION II. CLINICAL GUIDELINES

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

B. 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.

3

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 nonsynostotic 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 PA from MassHealth. Requests for PA must be accompanied by clinical documentation that supports the medical necessity for cranial orthoses, as described above, and must be submitted to MassHealth in accordance with 130 CMR 442.000 and 450.000. As part of the PA request, the provider of orthotics must obtain a written prescription and letter of medical necessity signed by the member's prescribing provider. The prescription and letter of medical necessity must meet the requirements at 130 CMR 442.000 and 450.000. Any additional clinical documentation supporting medical necessity must be submitted with the PA request.

Providers are strongly encouraged to submit PA requests electronically, and all information pertinent to the request must be submitted using the LTSS Provider Portal or by completing a [MassHealth Prior Authorization Request](#) form (PA-1) and attaching the documentation. Questions regarding portal access should be directed to the LTSS Provider Service Center by calling toll-free at (844) 368-5184.

Select References

1. Hutchison BL, Stewart AW, de Chalain T, Mitchell EA. [Serial developmental assessments in infants with deformational plagiocephaly](#). J Pediatr Child Health 2012 Mar; 48(3):274-8.
2. Hutchison BL, Stewart AW, Mitchell EA. [Deformational plagiocephaly: A follow-up of head shape, parental concern and neurodevelopment at ages 3 and 4 years](#). Arch Dis Child. 2011;96(1): 85-90.
3. Laughlin, J, Leurssen TG, Dias MS; Committee on Practice and Ambulatory Medicine, Section on Neurological Surgery. [Prevention and management of positional skull deformities in infants](#). Pediatrics. 2011; 128; 1236-1241.
4. Loveday BP, de Chalain TB. [Active counterpositioning or orthotic device to treat positional plagiocephaly?](#) J Craniofacial Surg. 2001; 12:308-313.
5. McGarry A, Dixon MT, Greig RJ, Hamilton DR, Sexton S, Smart H. [Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly](#). Dev Med Child Neurol. 2008, 50: 568–576.
6. Moss SD. [Nonsurgical, nonorthotic treatment of occipital plagiocephaly: What is the natural history of the misshapen neonatal head?](#) J Neurosurg. 1997; 87:667-70.
7. Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM. [Analysis of posterior plagiocephaly: Deformational versus synostotic](#). Plastic Reconstructive Surg. 1999; 103:371-380.
8. 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.
9. Teichgraeber JF, Ault JK, Baumgartner J, et al. [Deformational posterior plagiocephaly: Diagnosis and treatment](#). Cleft Palate-Craniofacial J. 2002; 39:582-586.
10. Hutchison BL, Stewart AW, de Chalain T, Mitchell EA. [Serial developmental assessments in infants with deformational plagiocephaly](#). J Pediatr Child Health 2012 Mar; 48(3):274-8.
11. Hutchison BL, Stewart AW, Mitchell EA. [Deformational plagiocephaly: A follow-up of head shape, parental concern and neurodevelopment at ages 3 and 4 years](#). Arch Dis Child. 2011;96(1): 85-90.
12. Laughlin, J, Leurssen TG, Dias MS; Committee on Practice and Ambulatory Medicine, Section on Neurological Surgery. [Prevention and management of positional skull deformities in infants](#). Pediatrics. 2011; 128; 1236-1241.
13. Loveday BP, de Chalain TB. [Active counterpositioning or orthotic device to treat positional plagiocephaly?](#) J Craniofacial Surg. 2001; 12:308-313.
14. McGarry A, Dixon MT, Greig RJ, Hamilton DR, Sexton S, Smart H. [Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly](#). Dev Med Child Neurol. 2008, 50: 568–576.
15. Moss SD. [Nonsurgical, nonorthotic treatment of occipital plagiocephaly: What is the natural history of the misshapen neonatal head?](#) J Neurosurg. 1997; 87:667-70.
16. Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM. [Analysis of posterior plagiocephaly: Deformational versus synostotic](#). Plastic Reconstructive Surg. 1999; 103:371-380.
17. 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.
18. Teichgraeber JF, Ault JK, Baumgartner J, et al. [Deformational posterior plagiocephaly: Diagnosis and treatment](#). Cleft Palate-Craniofacial J. 2002;39:582-586.

19. Hutchison BL, Stewart AW, de Chalain T, Mitchell EA. [Serial developmental assessments in infants with deformational plagiocephaly](#). J Pediatr Child Health 2012 Mar; 48(3):274-8.
20. Hutchison BL, Stewart AW, Mitchell EA. [Deformational plagiocephaly: A follow-up of head shape, parental concern and neurodevelopment at ages 3 and 4 years](#). Arch Dis Child. 2011;96(1): 85-90.
21. Laughlin, J, Leurssen TG, Dias MS; Committee on Practice and Ambulatory Medicine, Section on Neurological Surgery. [Prevention and management of positional skull deformities in infants](#). Pediatrics. 2011; 128; 1236-1241.
22. Loveday BP, de Chalain TB. [Active counterpositioning or orthotic device to treat positional plagiocephaly?](#) J Craniofacial Surg. 2001; 12:308-313.
23. McGarry A, Dixon MT, Greig RJ, Hamilton DR, Sexton S, Smart H. [Head shape measurement standards and cranial orthoses in the treatment of infants with deformational plagiocephaly](#). Dev Med Child Neurol. 2008, 50: 568–576.
24. Moss SD. [Nonsurgical, nonorthotic treatment of occipital plagiocephaly: What is the natural history of the misshapen neonatal head?](#) J Neurosurg. 1997; 87:667-70.
25. Mulliken JB, Vander Woude DL, Hansen M, LaBrie RA, Scott RM. [Analysis of posterior plagiocephaly: Deformational versus synostotic](#). Plastic Reconstructive Surg. 1999; 103:371-380.
26. 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.
27. Teichgraeber JF, Ault JK, Baumgartner J, et al. [Deformational posterior plagiocephaly: Diagnosis and treatment](#). Cleft Palate-Craniofacial J. 2002; 39:582-586.

These Guidelines are based on review of the medical literature and current practice in cranial orthoses. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; such readers are encouraged to contact their health care provider for guidance or explanation.

Revised Policy Effective: March 23, 2023

Approved by: _____



Jatin K. Dave, MD, MPH
Chief Medical Officer, MassHealth

Supersedes policy dated September 24, 2018