

Clinical Policy: Cranial Molding Orthosis

Reference Number: TX.CP.MP.516

Last Review Date: 03/23

[Coding Implications](#)

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Description

Cranial molding orthosis are used to treat members diagnosed with synostotic plagiocephaly a form of non-syndromic craniosynostosis. This policy provides the medical necessity criteria for cranial molding orthosis for the following products: STAR, STAR+PLUS, STAR Health, STAR Kids, and CHIP.

Policy/Criteria

- I. It is the policy of Superior HealthPlan that a cranial molding orthosis is **medically necessary** when the following criteria are met:
 - A. Member is between 3 months to 18 months of age; *and*
 - B. Following cranial vault remodeling surgery for synostosis.

- II. A second cranial molding orthosis is considered **medically necessary** when the following criteria are met:
 - A. Member is within 6 to 18 months of age;
 - B. Treatment with the initial device has been objectively effective;
 - C. The new device is necessary due to member's growth; and
 - D. Objective documentation indicates potential for additional clinical improvement.

- III. It is the policy of Superior HealthPlan that cranial molding orthosis is **not medically necessary and therefore is not a covered benefit** for the following indications:
 - A. Treatment of deformational plagiocephaly, because the effective use of a cranial molding orthosis for this diagnosis is controversial and has not been reliably documented in the medical literature.
 - B. Treatment of brachycephaly (i.e. a high cephalic index without cranial asymmetry), as it has not been reliably documented.

- IV. Cranial molding orthosis for congenital or acquired conditions members greater than 18 months old will be reviewed on a case-by-case basis by the Plan medical director.

Appendix

Definitions:

- Cranial Molding Orthosis - Cranial molding orthosis are usually comprised of an adjustable helmet or band that progressively molds the shape of the infant cranium by applying corrective forces to prominences while leaving room for growth in the adjacent flattened areas. A cranial molding orthosis may be medically necessary in the treatment of postsurgical synostosis in pediatric patients.

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- Synostotic Cranial Deformity - A asymmetrically shaped head may be synostotic or non-synostotic in etiology. Synostosis, defined as premature closure of the sutures of the cranium, may even result in functional deficits secondary to increasing intracranial pressure in an abnormally or asymmetrically shaped cranium. Synostotic deformities are addressed by surgical remodeling of the cranial vault.
- Non-Synostotic Plagiocephaly - Plagiocephaly without synostosis, also called positional or deformational plagiocephaly, can be associated with various environmental factors including, but not limited to, premature birth, restrictive intrauterine environment, birth trauma, torticollis, cervical anomalies, and sleeping position. It is estimated that about two-thirds of cases may correct spontaneously or after regular changes in sleeping position or following physiotherapy aimed at correcting neck muscle imbalance.

Coding Implications

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CPT® Codes	Description
N/A	

HCPCS® Codes	Description
S1040	Cranial molding orthosis

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	01/12	01/12
Change positional plagiocephaly to deformational plagiocephaly. Deleted definition for DME. Revised work process, signatories and references.	07/14	07/14
Removed work process and imbedded in attachment section. Added policy to reference list.	02/15	02/15
Removed work process attachment and placed in separate document. Updated Policy Criteria 2 (d). Grammatical changes. Updated References.	07/15	07/15

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Reviews, Revisions, and Approvals	Date	Approval Date
Grammatical edits. Updated references and signatories. Removed work process for authorization protocol. Removed dx code 756.0.	07/16	07/16
Updated product lines and review date.	07/17	07/17
Updated revision date, references and signatories. Removed “Important Reminder”.	07/18	07/18
Cranial remolding orthosis, synostotic cranial deformity, non-synostotic plagiocephaly descriptions moved to definitions. Grammatical edits. Updated signatories. Under criteria added objective documentation indicates potential for additional clinical improvement. Removed HCPCS code.	01/19	01/19
Updated to new template from TX.UM.10.16 (TX.CP.MP.516 nomenclature implementation). Added HCPCS S1040 code. Under section III. added “and therefore is not a covered benefit”. Updated references.	02/20	02/20
Annual review. Updated references.	03/21	03/21
Annual review. Updated references.	03/22	03/22
Annual review. Updated references. Added to Description for clarity “ <i>a form of nonsyndromic craniosynostosis</i> .”. Removed the ICD 10 table. Title corrected from “remolding” to molding and “orthoses” to orthosis.	03/23	03/23

References

1. Collet, Brent R, “Helmet Therapy for Positional Plagiocephaly and Brachycephaly,” *BMJ* 2014;348:g2906, May1, 2014.
2. Mawji, Aliyah, Robinson Vollman, Ardene, Hatfield, Jennifer, McNeil, Deborah A., and Sauvé, Reginald, “The Incidence of Positional Plagiocephaly: A Cohort Study,” *The American Academy of Pediatrics (AAP), Pediatrics*; originally published online July 8, 2013; DOI: 10.1542/peds.2012-3438.
3. Saint Louis, Catherine, “Helmets Do Little to Help Moderate Infant Skull Flattening, Study Finds,” *The New York Times*, May 1, 2014, page A18.
4. The American Academy of Pediatrics (AAP) Clinical Practice guidelines, “Prevention and Management of Positional Skull Deformities in Infant,” AAP Committee on Practice and Ambulatory Medicine, Section on Neurological Surgery, *Pediatrics* 2011;128;1236.
5. Van Wijk PhD, Renske, Van Vlimmeren, Leo, Groothuis-Oudshoorn, Catharina, Van der Ploeg, Catharina, IJzerman, Maartan, and Boere-Boonekamp, Magda, “Helmet therapy in infants with positional skull deformation: randomized controlled trial”, *BMJ* 2014;348:g2741 doi: 10.1136/bmj.g2741, May 1 2014.
6. Texas Medicaid Provider Procedures Manual, Durable Medical Equipment, Medical Supplies, and Nutritional Products Handbook, 2.2.19.3 Cranial Molding Orthosis, February 2023

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted



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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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