Driscoll Health Plan
Medical Necessity Guideline

Medical Necessity Guideline: Cranial Molding Orthoses	**Creation Date:** 07/13/2014	**Review Date:** 05/29/2025	**Effective Date:** 07/17/2025

PURPOSE:

To define authorization requirements for Cranial Molding Orthoses.

LINE OF BUSINESS: STAR, STAR Kids, and CHIP

DEFINITIONS:

Cranial Molding Orthoses (aka Helmets or CMOs) - prefabricated or custom-fitted and custom-molded devices that allow for growth in certain regions of the cranium and restrict growth in others. CMOs do not alter the magnitude of intrinsic brain growth but rather its direction. Designs may be active or passive, rigid or flexible, or hinged or circumferential. Symmetrical growth is achieved by consistent evaluation and adjustments to the CMO based on the child's head shape and growth patterns.

Craniosynostosis - a condition in which one or more of the sutures close too early, causing problems with normal brain and skull growth. Premature closure of the sutures may also cause the pressure inside of the head to increase and the skull or facial bones to change from a normal, symmetrical appearance. (1)

Plagiocephaly or "flat head" - a condition where an infant's head has a flat spot or is misshapen. There are two main types: Positional plagiocephaly develops when an infant's soft skull becomes flattened due to repeated pressure on one part of the head (commonly from the positioning of the infant on its back). Synostotic plagiocephaly is related to craniosynostosis. (1)

GUIDELINE:

Prior Authorization and Documentation Requirements

- CMO is recommended or requested by a neurosurgeon or craniofacial surgeon.
- Referrals from other physician specialists will be considered case-by-case by medical director review.
- Orthoses will be approved with a diagnosis of synostotic plagiocephaly.
- The member is 3 through 18 months.
- Clinical documentation, including skull measurements and photographs, must be provided by the treating physician and referring neurosurgeon or craniofacial surgeon documenting synostotic plagiocephaly.

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- Requests for a cranial molding orthosis for congenital conditions that are not outlined in this section may be considered by the Medical Director on a case-by-case basis with documentation of medical necessity. The Medical Director may consider special requests for positional plagiocephaly of an extreme nature in consultation with the requesting neurosurgeon or craniofacial surgeon.
- The benefit limitation is one device per lifetime.
- Additional devices beyond the one device per lifetime benefit may be considered with documentation of all the following:
  - The initial device was obtained to treat synostotic plagiocephaly.
  - Treatment with the device has been effective.
  - The new device is needed due to growth

Non-covered services:

The CMO is not for cosmetics - the definition for cosmetic, as it applies to cranial molding orthosis, includes surgery or other services used primarily to improve the appearance and not to restore or correct significant deformity resulting from disease, or trauma, congenital or developmental anomalies, or previous therapeutic process. A CMO used for the treatment of positional plagiocephaly is considered cosmetic and, therefore, is not a benefit of Texas Medicaid. [2]

The effective use of a cranial molding orthosis for treating brachycephaly, or a high cephalic index without cranial asymmetry that has not been documented, is not medically necessary and is, therefore, not a benefit of Texas Medicaid. [2, 3]

BACKGROUND:

Driscoll Health Plan (DHP) requires prior authorization and medical director review of all requests for Cranial Molding Orthoses (CPT S104). DHP follows the guidelines listed in the Texas Medicaid Provider Procedures Manual (TMPPM).

Cranial Molding Orthoses (CMOs) are used to redirect the growth of the skull bones and reduce cranial asymmetry in infants with a positional cranial deformity. CMOs are prefabricated or custom-fitted and custom-molded devices that allow for growth in some cranium areas and restrict growth in others. CMOs do not alter the magnitude of intrinsic brain growth but rather its direction. Designs may be active or passive, rigid or flexible, or hinged or circumferential. Symmetrical growth is achieved by consistent evaluation and adjustments to the CMO based on the child's head shape and growth patterns. [1, 3, 4, 5] The devices are most effective for ages 3 to 18 months. Often more than one device is required as the skull changes shape.

The use of CMOs to treat Positional Cranial Deformity (PCD) is controversial, primarily due to the low quality of evidence. Guideline recommendations were developed without high-quality evidence. The clinical benefit of CMO treatment over repositioning therapy is also controversial - evidence from one controlled study did not find a statistical difference in efficacy between CMO versus the control group. Mild complications are common. [1, 3, 4]
Hayes ® , a comprehensive review of evidence-based studies and reports, indicates the efficacy of CMOs for the treatment of PCD is unclear and assigns a C rating (this Rating reflects uncertainty regarding the clinical benefit of CMOs raised by results from a recent randomized controlled trial. A rating of D2 (lack of evidence) is assigned to treat very severe positional deformities, treat patients with head deformities due to underlying congenital conditions (e.g., muscular torticollis, hydrocephalus), and as a means of preventing or correcting neurodevelopmental delay or disability.

PROVIDER CLAIMS CODES:

ICD 10		
Q67.3	Q75.0	Q75.8

CPT
S1040

REFERENCES:

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2. Texas Medicaid Provider and Procedure Manual (Current Edition), Durable Medical Equipment, and Nutritional Supplies Handbook, 2.2.19.3 Cranial Molding Orthosis, May 2024.
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5. Graham T, Adams-Huet B, Gilbert N, Witthoff K, Gregory T, Walsh M. Effects of Initial Age and Severity on Cranial Remolding Orthotic Treatment for Infants with Deformational Plagiocephaly. *J Clin Med*. 2019;8(8):1097.
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DOCUMENT HISTORY:

DHP Committee that Approved	*Review Approval Date (last 5 years)*				
Medical Director	05/24/2022	05/23/2023	05/24/2024	05/29/2025	
CMO	06/07/2022	06/06/2023	06/11/2024	06/10/2025	
Medical Policy Workgroup	06/07/2022	06/06/2023	06/11/2024	06/10/2025	
Utilization Management & Appeals	06/21/2022	06/20/2023	06/18/2024	06/17/2025	
Provider Advisory Committee (PAC)	06/17/2022	06/09/2023	07/01/2024	06/24/2025	
Clinical Management Committee	06/24/2022 & 08/23/2022	07/20/2023	07/24/2024	07/01/2025	
Executive Quality Committee	06/28/2022	07/25/2023	07/30/2024	07/17/2025	

Document Owner	*Organization*	*Department*
Dr. Fred McCurdy, Medical Director	Driscoll Health Plan	Utilization Management

Review/Revision Date	*Review/Revision Information, etc.*
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11/28/2016	Updated reference
11/28/2017	Updated reference
11/16/2018	Updated reference
11/24/2019	Converted to new format and updated reference
05/11/2020	Update references and formats – Hayes Addition and codes
06/05/2020	Updated Background
06/16/2020	Minor format
05/14/2021	Full review and update of references – April 28 Update from Hayes!

05/17/2022	Review and update – Dr. Thomas Morris
05/24/2022	Review and final editing by Dr. Fred McCurdy
05/23/2023	Updated TMPPM reference after review by Drs. Thomas Morris and Fred McCurdy
05/24/2024	Reviewed and revised by Dr. Fred McCurdy
05/13/2025- 05/29/2025	Annual review and revision initiated 5/13/2025 and completed on 05/29/2025 by Tamara Gonzalez PT, Paige Tietze SLT, and Dr Dan Doucet