Plagiocephaly and Craniosynostosis Treatment

Policy Number: SURGERY 067.26
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Instructions for Use

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Related Policies

- Cosmetic and Reconstructive Procedures
- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements

Coverage Rationale

Cranial orthotic devices are proven and medically necessary for treating infants following craniosynostosis surgery or for nonsynostotic (nonfusion) deformational or positional plagiocephaly. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Orthoses, Cranial Remodeling.

Click here to view the InterQual® criteria.

For surgical treatment to repair craniosynostosis (CPT Code 21175), refer to the Clinical Policy titled Cosmetic and Reconstructive Procedures.

For repair or replacement of cranial orthoses, refer to the Clinical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

HCPCS Codes*	Required Clinical Information
Cranial Orthosis	

S1040	Medical notes documenting the following, when applicable:
	• Current prescription from physician
	• Diagnosis and indication(s) for cranial orthosis
	• General physical exam including presence or absence of torticollis
	• At least one of the following:
	  ○ Cranial vault asymmetry index (CVAI)
	  ○ Cephalic index (CI)
	  ○ Transcranial diameter difference (TDD)
	  ○ Cranial vault asymmetry (CVA)

HCPCS Codes*	Required Clinical Information
Cranial Orthosis	
S1040	○ Children's Healthcare of Atlanta (CHOA) level ○ For more details about the definition of these measurements, refer to the InterQual® criteria informational notes ● Documentation of treatments tried, failed, or contraindicated; include the dates, duration, and reason for discontinuation, including: ○ Repositioning ○ Physical or occupational therapy ● Orthotist notes to include the following: ○ Equipment quote with billing codes ○ Reason for the orthotic ○ Anthropometric measurements ● Date of planned or completed craniosynostosis surgery, if applicable ● Physician treatment plan, including plan to treat torticollis with cranial orthosis ● In addition to the above, also provide the following for a request for continuation of treatment with a new cranial orthotic: ○ Age of current orthotic ○ Reason for replacement ○ Adjustments/modifications to current cranial helmet if applicable ○ Compliance with wear

*For code description, refer to the Applicable Codes section.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CDT Code	Description
D5924	Cranial prosthesis

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HCPCS Code	Description
L0112	Cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated
L0113	Cranial cervical orthotic, torticollis type, with or without joint, with or without soft interface material, prefabricated, includes fitting and adjustment
S1040	Cranial remolding orthotic, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Cranial orthoses are classified by the FDA as Class II devices. This classification requires special controls, including prescription use, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, and instructions for physicians and parents). They are intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-

shaped heads. The FDA has approved a large number of cranial orthoses. Additional information, under product code MVA, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 26, 2023)

Policy History/Revision Information

Date	Summary of Changes
11/01/2023	**Related Policies** • Removed reference link to the Clinical Policy titled *Upper Extremity Myoelectric Prosthetic Devices* **Documentation Requirements** • Updated list of required clinical information; replaced: ○ "Diagnosis and *reason* for the *orthotic*" with "diagnosis and *indication(s)* for *cranial orthosis*" ○ "Physical exam *related to support the need of the orthotic; include the neurological, circulatory, skin, and musculoskeletal examination that supports the request, as well as* presence or absence of torticollis" with "*general* physical exam including presence or absence of torticollis" ○ "Documentation of treatments tried, failed, or contraindicated; include the dates and reason for discontinuation" with "documentation of treatments tried, failed, or contraindicated; include the dates, *duration*, and reason for discontinuation" ○ "Orthotist notes to include equipment quote with billing codes *and cost*" with "orthotist notes to include equipment quote with billing codes" ○ "Date *and type of injury/*surgery, if applicable" with "date *of planned or completed craniosynostosis* surgery, if applicable" ○ "Provide [the listed additional criteria] for a *replacement* request" with "Provide [the listed additional criteria] for a request *for continuation of treatment with a new cranial orthotic*" **Supporting Information** • Archived previous policy version SURGERY 067.25

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.