Plagiocephaly and Craniosynostosis Treatment

Policy Number: 2023T0031BB
Effective Date: April 1, 2023

Application

UnitedHealthcare Commercial
This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange
This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Nevada, and New York.

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 Medical Policy titled Cosmetic and Reconstructive Procedures.

For repair or replacement of cranial orthoses, refer to the Medical 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.
### Required Clinical Information

<table>
<thead>
<tr>
<th>HCPCS Code*</th>
<th>Description</th>
</tr>
</thead>
</table>
| S1040       | Medical notes documenting the following, when applicable:  
  - Current prescription from physician  
  - Reason for the orthotic  
  - Diagnosis  
  - 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  
  - At least one of the following:  
    - Cranial vault asymmetry index (CVAI)  
    - Cephalic index (CI)  
    - Transcranial diameter difference (TDD)  
    - Cranial vault asymmetry (CVA)  
    - 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 and reason for discontinuation, including:  
    - Repositioning  
    - Physical or occupational therapy  
  - Orthotist notes to include the following:  
    - Equipment quote with billing codes and cost  
    - Reason for the orthotic  
    - Anthropometric measurements  
  - Date and type of injury/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 replacement request:  
    - 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 and Guidelines may apply.

<table>
<thead>
<tr>
<th>CDT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>D5924</td>
<td>Cranial prosthesis</td>
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*CDT® is a registered trademark of the American Dental Association*

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>L0112</td>
<td>Cranial cervical orthosis, congenital torticollis type, with or without soft interface material, adjustable range of motion joint, custom fabricated</td>
</tr>
<tr>
<td>L0113</td>
<td>Cranial cervical orthotic, torticollis type, with or without joint, with or without soft interface material, prefabricated, includes fitting and adjustment</td>
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### HCPCS Code and Description

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<tr>
<td>S1040</td>
<td>Cranial remolding orthosis, pediatric, rigid, with soft interface material, custom fabricated, includes fitting and adjustment(s)</td>
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</table>

### 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/pmncfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncfm). (Accessed August 11, 2022)

### Policy History/Revision Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tbody>
<tr>
<td>04/01/2023</td>
<td><strong>Template Update</strong></td>
</tr>
<tr>
<td></td>
<td>● Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans (no change to coverage guidelines)</td>
</tr>
<tr>
<td></td>
<td>● <strong>Added Application</strong> section to indicate this Medical Policy applies to:</td>
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<td></td>
<td>o All UnitedHealthcare Commercial benefit plans</td>
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**Supporting Information**

- Archived previous policy versions 2023T0031AA and IEXT0031.09

### Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare 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 reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncfm)).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical 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.