Cranial Orthotic Devices & Protective Helmets
Policy Number: PG0120
Last Review: 06/12/2018

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
_ Facility

DESCRIPTION
Cranial orthotic devices are usually in the shape of an adjustable helmet or band, which progressively molds the shape of the infant cranium by applying corrective forces to prominences while leaving room for growth in the adjacent flattened areas. Cranial orthotic devices are used for misshapen flattened skull bones, caused by a number of reasons; prematurity, birth trauma, repetitive sleeping positions, restrictive intrauterine positioning, torticollis, etc. Treatment is typically initiated around five to six months of age and continues for an average of four to six months. Cephalic index is the ratio of the maximum width of the head multiplied by one hundred divided by its maximum length (i.e., in the horizontal plane, or front to back).

Several FDA-approved orthoses are available and include but are not limited to the following devices:
- Dynamic Orthotic Cranioplasty (DOC™) Band, Cranial Technologies, Inc. (Phoenix, AZ)
- Ballert Cranial Molding Helmet, Ballert Orthopedic (Chicago, IL)
- RHS Cranial Helmet, Restorative Health Services, Inc. (Nashville, TN)
- Hanger Cranial Band, Hanger Orthopedic Group, Inc. (Bethesda, MD)
- P.A.P. Orthosis (Plagiocephalic Applied Pressure Orthosis), Fit Well Prosthetic Orthotic Center (Personal Performance Medical) (Salt Lake City, UT).
- O & P Cranial Molding Helmet, Orthotic and Prosthetic Lab, Inc. (Evansville, IN)
- Cranial Solutions Orthosis CSO, Cranial Solutions (Pompton Lakes, NJ)
- Cranial Symmetry System, Beverly Hills Prosthetics Orthotics, Inc. (Los Angeles, CA)
- STARband™, STARlight™ Cranial Remolding Orthosis, and the Clarren Helmet, Orthomerica Products, Inc. (Newport Beach, CA)
- ECA orthosis, Eastern Cranial Affiliates, Infinite Technologies (Arlington, VA)
- COPC Band, Center for Orthotic and Prosthetic Care of KY (Louisville, KY)

Protective helmet codes were created to identify these items as helmets within medical surgical supplies, rather than a specific orthotic and prosthetic device. However, CMS assigned its classification as orthotic, even though it is listed as an A-code. Cranial helmets are used to prevent a head injury when medical conditions affecting balance could lead to a fall, or for recent brain/head surgery and a helmet is required to protect the surgical site.
POLICY

HMO, PPO, Individual Marketplace
Cranial orthotic devices (L0112, L0113, and S1040) require prior authorization.
Protective helmets (A8000, A8001, A8002, A8003, and A8004) do not require prior authorization.

Elite/ProMedica Medicare Plan
Cranial orthotic devices (L0112, L0113) require prior authorization.
Code S1040 is Non-Medicare.
Protective helmets (A8000, A8001, A8002, A8003, and A8004) do not require prior authorization.

Advantage
Cranial orthotic devices (S1040) require prior authorization.
Protective helmets (A8000, A8001, A8002, and A8003) do not require prior authorization.
Codes A8004, L0112, L0113 are non-covered.

(See allowable limits and terms of coverage below)

COVERAGE CRITERIA

A. Cranial orthotic devices (L0112, L0113, S1040)
1. A cranial orthotic remolding device is covered for treatment of positional (non-synostotic) plagiocephaly only if all of the following criteria are met:
   a. Member is at least three months of age but not greater than eighteen months of age; and
   b. Marked asymmetry has not been substantially improved following conservative therapy of at least two months duration with cranial repositioning therapy and/or physical therapy; and
   c. Asymmetry of the cranial base as documented by any of the following:
      • Skull base asymmetry: At least six millimeter (mm) right/left discrepancy measured subnasally to the tragus, defined as the cartilaginous projection of the auricle at the front of the ear; or
      • Cranial vault asymmetry: At least a ten mm right/left discrepancy measured from the frontozygomaticus point (identified by palpation of the suture line above the upper outer corner of the orbit) to the euryon, defined as the most lateral point on the head located in the parietal region; or
      • Asymmetry of the orbitotragial distances, as documented by at least a four mm right/left asymmetry.
2. A cranial orthotic remolding device is covered for treatment of positional (non-synostotic) braciocephaly if the cephalic index is greater than ninety-one percent.
3. A cranial orthotic remolding device is covered for the treatment of positional (non-synostotic) scaphocephaly if the cephalic index is less than seventy-five percent.
4. A cranial orthotic remolding device is covered for treatment of synostotic deformity if all of the following criteria are met:
   a. Member is between the ages of birth and eighteen months; and
   b. Premature closing of the cranial structures is documented by treating prescriber and surgery with post-operative treatment including remolding orthotic helmeting is medically indicated and documented in the member’s medical record.
5. All documentation supporting the above medical criteria must be kept in the provider's file and be available for review upon request.
6. Cranial orthotic remolding devices must be prescribed by a prescriber actively involved in managing the member's medical care through a comprehensive plan of care, which addresses the need for a cranial orthotic remolding device. This prescription must contain the original signature of the ordering prescriber that attests to medical necessity of this device.

Non-coverage determination
A cranial orthotic remolding device is non-covered for members who cannot document an appropriate medical need based on the provisions of this policy.

Dispensing
1. The following components are considered “inclusive” with any payment made by Paramount for a cranial orthotic remolding device on behalf of a member, cannot be submitted for separate reimbursement and must be dispensed and/or maintained by the billing provider:
a. Labor;
b. Orthotic remolding device;
c. Casting, fitting, or measuring fees;
d. Charges for travel; and
e. Charges for shipping and mailing.

2. Providers must document that the member’s primary caregiver is instructed as to the proper use and wear of the cranial orthotic remolding device and documentation of this instruction must be kept in the provider’s file.

3. Any dispensed cranial orthotic remolding device must be of a type and fabricated at a facility approved for member use as an approved class II medical device by the food and drug administration (FDA).

4. Any provider dispensing and fitting a cranial remolding orthotic device must have the appropriate documentation on file that demonstrates the appropriate training necessary to fit the device properly.

5. Members are eligible for only one cranial orthotic remolding device per lifetime.

B. Protective helmets (A8000-A8004)
   Cranial helmets may be a covered benefit as a protective device for medical conditions (e.g. seizure disorder, post-operative protection). Protective helmets used for sports or recreation (e.g. bike or ski helmets) are not a covered benefit.

HMO, PPO, Individual Marketplace
Cranial orthotic devices (L0112, L0113, S1040) - allow only one per lifetime
Protective helmets (A8000, A8001, A8002, A8003, A8004) - allow only one per year

Elite/ProMedica Medicare Plan
Cranial orthotic devices (L0112, L0113) - allow only one per lifetime
Protective helmets (A8000, A8001, A8002, A8003, A8004) - allow only one per year

Advantage
Cranial orthotic device (S1040) - allow only one per lifetime
Protective helmets (A8000-A8003) - allow only one per year

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>HCPCS CODES</th>
<th>Description</th>
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<tbody>
<tr>
<td>A8000</td>
<td>Helmet, protective, soft, prefabricated, includes all components and accessories</td>
</tr>
<tr>
<td>A8001</td>
<td>Helmet, protective, hard, prefabricated, includes all components and accessories</td>
</tr>
<tr>
<td>A8002</td>
<td>Helmet, protective, soft, custom fabricated, includes all components and accessories</td>
</tr>
<tr>
<td>A8003</td>
<td>Helmet, protective, hard, custom fabricated, includes all components and accessories</td>
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<tr>
<td>A8004</td>
<td>Soft interface for helmet, replacement only</td>
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<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>
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<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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<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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REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 02/15/2007
02/01/08: No change
12/01/08: Added code
01/01/09 added procedure code L0113
09/01/11: Updated Advantage coverage
08/12/14: S1040 is now covered for PPO, A8002, A8003, A8004 are now covered for HMO, PPO, Individual Marketplace & Elite. L0112, L0113, S1040 requires prior authorization for all product lines. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
08/08/17: Clarified that code S1040 is Non-Medicare. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
06/12/18: For Advantage, protective helmets (A8002, A8003) are now allowed only one per year per ODM guidelines versus per medical event. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
12/15/2020: Medical policy placed on the new Paramount Medical policy format

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.