



Care1st Health Plan Arizona, Inc.

Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

Cranial Remodeling With Orthotic Devices

Policy Number: HS-009

Original Effective Date: 12/6/2007

**Revised Date(s): 4/22/2009; 8/12/2011;
4/5/2012; 4/11/2013; 4/3/2014; 4/2/2015;
4/7/2016; 4/6/2017; 3/1/2018**

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Cranial orthotic devices are used in infants for the treatment of positional plagiocephaly, deformation of the head that results from external pressure applied to the soft infant skull. The deformity can begin in utero but most commonly is associated with infants sleeping or lying on their backs, especially if the head is turned in the same direction for long periods of time. If detected during the first few months of life, frequent repositioning of the baby's head combined with prone positioning during waking hours can correct the condition in the majority of children. In some babies, congenital muscular torticollis, or weakness of the neck muscles, can be a predisposing factor for development of positional plagiocephaly. For these children, physical therapy and massage to lengthen the neck muscles may be

required in addition to repositioning. If the cranial asymmetry is not detected early or if repositioning therapy is unsuccessful, then cranial orthotic devices, such as adjustable head bands or plastic helmets, can be used to gradually mold the infant's skull back into place over a period of weeks or several months.

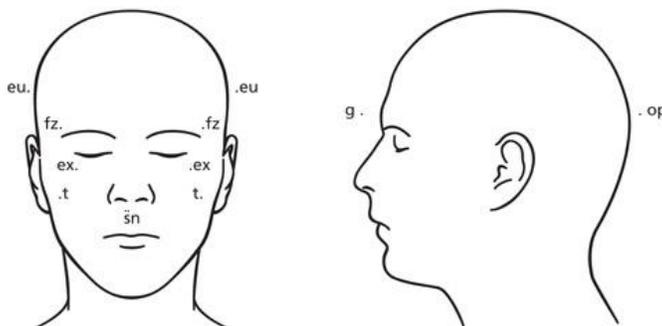
Positional plagiocephaly must be differentiated from craniosynostosis, a condition in which one or more of the sutures of an infant's skull close prematurely, resulting in a misshapen head that grows progressively more deformed as the child grows. True craniosynostosis occurs much less frequently than positional plagiocephaly and is currently estimated to affect less than 3 infants per 100,000 births. Craniosynostosis usually requires surgical treatment to reshape the bone in the affected area, while surgical treatment is only rarely indicated for positional plagiocephaly. In the past, many infants with cranial asymmetry were incorrectly diagnosed with craniosynostosis, and only recently have neurosurgeons and craniofacial surgeons begun to recognize that most of these individuals do not require surgery, especially if the condition is diagnosed during the first year of life.¹

Most infants improve if the appropriate maneuvers are conducted during a 2-3 month time period. These include:

- Positioning the infant so the rounded side of the head is placed dependent against the mattress during sleep
- Positioning the child in the crib to look away from the flattened side to see parents and others in the room
- Placing the infant in the prone position during wakeful periods
- Neck exercises at each diaper change to prevent or treat torticollis

Anthropometric Evaluation

Anthropometric data, or the measurements used to evaluate abnormal head shape by measuring the distance in mm from one pre-designated point on the face or skull to another, (see diagram below) must verify that a moderate to severe plagiocephaly is documented by an experienced physician. The most significant measurements are skull base asymmetry, cranial vault asymmetry, orbitotragial depth and cephalic index.



A difference of asymmetry greater than 6 mm between anthropometric measurements (see diagram above) in any of the anthropometric data in the first column of the following table warrants coverage of a trial of orthotic banding to correct the craniofacial deformity:

Anthropometric Data	Measurement	Measures
Cranial base (sn-t on same side)	from right and left subnasal point (sn) to tragus (t)	measures maxillary depth or right and left morphological face height
Cranial vault (fz R-euL, fz L-euR)	from frontozygomaticus point (fz) on one side of face to euryon (eu)	measures cranial vault asymmetry
Orbitotragial depth (ex-t, R, L)	from exocanthion point (ex) to tragus (t)	measures orbito-tragion depth (exocanthion)

For brachycephaly evaluation, a cephalic index 2 standard deviations below mean (head narrow for its length) or 2 standard deviations above mean (head wide for its length) warrants coverage of a trial of orthotic banding to correct the craniofacial deformity in a child after 4 months of age and before 12 months of age.

Head width (eu - eu)	from euryon (eu) on one side of head to euryon (eu) on the other side	measures greatest transverse diameter or maximal head width
Head length (g-op)	from glabella point (g) to opisthocranium (op)	measures maximal head depth or length

$$\text{Cephalic index} = \frac{\text{Head width (eu - eu)} \times 100}{\text{Head length (g - op)}}$$

Sex	Age	-2SD	-1SD	Mean	+1SD	+2SD
Male	16 days to 6 months	63.7	68.7	73.7	78.7	83.7
	6 - 12 months	64.8	71.4	78.0	84.6	91.2
Female	16 days to 6 months	63.9	68.6	73.3	78.0	82.7
	6-12 months	69.5	74.0	78.5	83.0	87.5

The American Academy of Pediatrics (AAP) issued an update in 2011 to a 2003 clinical report regarding management for the prevention of positional skull deformities in infants.² Highlights from the report include the following recommendations:

- Offering counseling to new parents during the first four weeks of age which include instruction on laying the infant down to sleep in the supine position, alternating positions (i.e., left and right occiputs).
- When awake and being observed, the infant should spend time in the prone position (“tummy time”) for at least 30 to 60 minutes/day.
- Monitor head shape closely until there is confidence that improvement will continue, usually when the infant is old enough to sit, crawl, and spend less time on his or her back and until any associated torticollis is completely corrected.
- Prolonged placement indoors in car safety seats and swings should be discouraged.

Additional highlights from the 2003 report include:

- If a deformational plagiocephaly is diagnosed, the AAP recommends mechanical adjustments, including positioning so that the rounded side of the head is placed against the mattress and a change in the layout of the room to cause a child to look away from the flattened side of the head to see parents or others in room.
- For torticollis, neck motion exercises are recommended. If these therapies prove unsuccessful, the AAP recommends visiting a neurosurgeon to ensure a proper diagnosis and direct subsequent management, including molding helmets and surgery. The AAP reports that the best response for helmets occurs in children aged 4 to 12 months due to the malleability of the infant skull. Surgery is only indicated when the deformities are severe and resistant to nonsurgical interventions.³

POSITION STATEMENT

Applicable To:

- Medicaid
- Medicare

Cranial remodeling with orthotic devices (helmets or bands) for members with moderate to severe positional (nonsynostotic) plagiocephaly **is considered medically necessary** when ALL of the following criteria are met:

- 4- Member has been diagnosed with a condition that occurs with plagiocephaly such as:
 - Premature birth; **OR**

- Restrictive intrauterine positioning; **OR**
- Cervical abnormalities; **OR**
- Birth trauma; **OR**
- Torticollis (shortening of the sternocleidomastoid muscle); **OR**
- Sleeping positions

AND,

2. Remodeling is initiated at 4-12 months of age; **AND**
3. A 2-month trial of conservative therapy (repositioning of the head such that the child lies opposite to the preferred position) has failed to improve the deformity and is judged unlikely to do so; **AND**
4. There is photographic evidence supporting moderate to severe positional plagiocephaly; **AND**
5. There is documentation of **EITHER** of the following criteria*:
 - Cephalic index \pm at least two standard deviations from the mean for the appropriate gender/age; **OR**
 - Asymmetry of 6 mm or more in ONE of the following measures:
 - Cranial vault; **OR**
 - Skull base; **OR**
 - Orbitotragial depth

* See Background section for more information on these anthropometric measurements.

Cranial remodeling with orthotic devices (helmets or bands) for members with (754.0 or 756.0) synostotic plagiocephaly (craniosynostosis) **is considered medically necessary following surgical correction.**

CODING

CPT® Codes – No applicable codes.

Covered HCPCS Codes *This list may not be all inclusive.*

- A8000** Helmet, protective, soft, prefabricated includes all components and accessories
- A8001** Helmet, protective, hard, prefabricated, includes all components and accessories
- A8002*** Helmet, protective, soft, custom fabricated, includes all components and accessories
- A8003*** Helmet, protective, hard, custom fabricated, includes all components and accessories
- A8004** Soft interface for helmet, replacement only
- L0112*** Cranial cervical orthotic, 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 join, with or without soft interface material, pre-fabricated, includes fitting and adjustment.
- S1040*** Cranial remolding orthotic, pediatric, rigid with soft interface material, custom fabricated, includes fitting and adjustments

*Note: Covered when medically necessary and used to report custom fabricated cranial orthotic devices for cranial remolding.

Covered ICD-10-CM Diagnosis Codes ((This list may not be all inclusive))

- Q67.3** Plagiocephaly
- Q75.0** Craniosynostosis
- Q75.9** Congenital malformation of skull and face bones, unspecified

Secondary Diagnosis Codes Associated with Phagiocephaly

- M43.6** Torticollis
- M95.2** Other acquired deformity of head
- M95.3** Acquired deformity of neck
- M99.80** Other biomechanical lesions of head region

M99.81	Other biomechanical lesions of cervical region
P07.00-P07.30	Extreme immaturity and other preterm infants
P13.0-P13.9	Birth injury to skeleton (P13)
Q18.8	Other specified congenital malformations of face and neck
Q67.0	Congenital facial asymmetry
Q67.1	Congenital compression facies
Q67.2	Dolichocephaly
Q67.4	Other congenital deformities of skull, face and jaw
Q68.0	Congenital deformity of sternocleidomastoid muscle
Q87.0	Congenital malformation syndromes predominately affecting facial appearance

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Cranial orthotic devices for the treatment of positional cranial deformity. Hayes Directory Web site. <http://www.hayesinc.com>. Published July 17, 2014. Accessed April 5, 2016. This is an updated version of a prior title published in 2010.
2. American Academy of Pediatrics. Errata: prevention and management of positional skull deformities in infants. 2011. *Pediatrics*;129(3):595.
3. Persing J, James H, Swanson J, Kattwinkel J, Committee on Practice and Ambulatory Medicine, Section on Plastic Surgery and Section on Neurological Surgery. American Academy of Pediatrics clinical reports. Guidance for the clinician in rendering pediatric care: prevention and management of positional skull deformities in infants. 2003. *Pediatrics*;112(1):199-202.
4. Laughlin J, Luerssen TG, Dias MS, Committee on Practice and Ambulatory Medicine, Section on Neurological Surgery. Clinical report: prevention and management of positional skull deformities in infants. 2011. *Pediatrics*;128(6):1236-1241.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
3/1/2018	<ul style="list-style-type: none"> • Approved by MPC. No changes.
4/6/2017	<ul style="list-style-type: none"> • Approved by MPC. Coding changes only.
4/7/2016, 4/2/2015, 4/3/2014, 4/11/2013	<ul style="list-style-type: none"> • Approved by MPC. No changes.
4/5/2012	<ul style="list-style-type: none"> • Approved by MPC. Added 2003, 2011 recommendations by the Am. Academy of Pediatrics.
12/1/2011	<ul style="list-style-type: none"> • New template design approved by MPC.
8/12/2011	<ul style="list-style-type: none"> • Approved by MPC. No changes.