

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.

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

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

HealthEase of Florida, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.



Cranial Remodeling with Orthotic Devices

Guideline Number: HS-009

Original Effective Date: 12/6/2007

Revision Date: 4/22/2009

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. 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 Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. 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.

Clinical Coverage Guideline HS-009

Cranial Remodeling with Orthotic Devices

Original Effective Date: 12/6/2007

Revised Date(s): 4/22/2009

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. 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 Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines.

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.

CLINICAL COVERAGE GUIDELINE

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:

1. Positional plagiocephaly is associated with **ANY** of the following:

- 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 synostotic plagiocephaly (craniosynostosis) is considered medically necessary following surgical correction.

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 (Hayes, 2004).

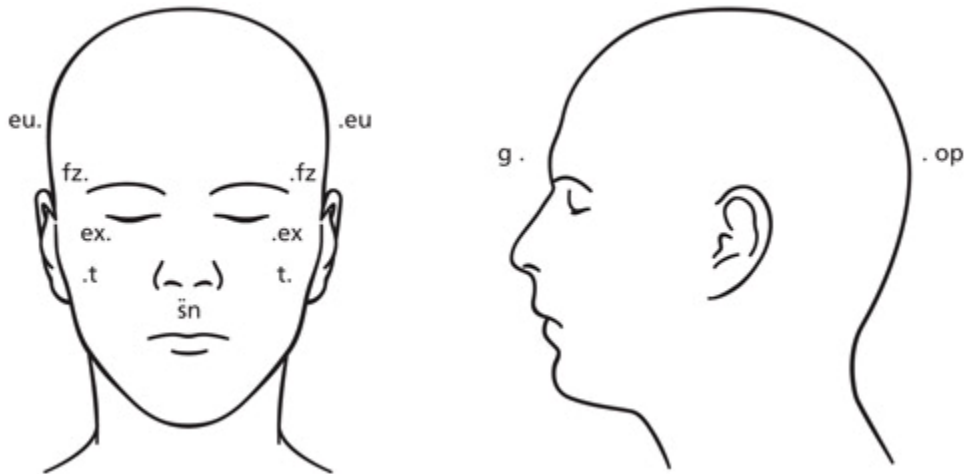
Conservative Treatment

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 frontozygomatic 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

CODING

CPT® Codes

No applicable codes

ICD-9 Procedure Codes

No applicable codes

Covered HCPCS Codes

- 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, prefabricated, includes fitting and adjustment.
- S1040*** Cranial remolding orthotic, 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-9-CM Diagnosis Codes

- 723.5** Torticollis, unspecified; Contracture of Neck
- 738.19** Other Acquired Deformity of Head
- 738.2** Acquired Deformity of Neck
- 744.89** Other specified anomalies of face and neck
- 754.0** Certain congenital musculoskeletal deformities of skull, face, and jaw; Plagiocephaly
- 754.1** Certain congenital musculoskeletal anomalies of sternocleidomastoid muscle; Contracture
- 756.0** Other congenital musculoskeletal anomalies of skull and face bones; Craniosynostosis
- 765.00 - 765.19** Extreme Immaturity and Other Preterm Infants
- 767.3** Birth Trauma, Other Injuries to Skeleton, i.e. Skull
- V48.6** Disfigurements of head

*Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©

REFERENCES

1. Hayes, Inc. Hayes Directory, Cranial Orthotic Devices. March 5, 2004.
2. American Academy of Pediatrics Clinical Reports. Guidance for the Clinician in Rendering Pediatric Care. Persing, J. et al. Committee on Practice and Ambulatory Medicine, Section on Plastic Surgery; and Section on Neurological Surgery. Prevention and Management of Positional Skull Deformities in Infants. Pediatrics, Vol. 112 (1), July, 2003.
3. Institute for Clinical Systems Improvement (ICSI) Technology Assessment Report #82. Prepared under the Direction of the Technology Assessment Committee (Robert Wood, Leader). Cranial Orthoses for Deformational Plagiocephaly. March, 2004.