

Subject: Request for Review of Coverage for Cranial Orthosis

To Whom it May Concern:

We are responding to a letter we received from XXXX XXXX, RN, DME Patient Care Coordinator, dated 21 February 2003 regarding denial of coverage for treatment of our son's plagiocephaly with the Dynamic Orthotic Cranioplasty (DOC) Band (attachment 1).

We wish we could say we were surprised by this denial but we were not. Through a support group network for plagiocephaly we have come in contact with many others whose health insurers denied them coverage for cranial orthosis. We have found that the people who get coverage are those who appeal multiple times and file grievances with their state regulatory agency. Therefore, we are asking Tricare to review this decision and consider the following information:

Enclosed is a letter of medical necessity from Dr. Amy XXXXXX, Baby X's pediatrician (attachment 3). To quote from Dr. XXXXXX's letter, "...the most likely complication of plagiocephaly is psychosocial because of the obvious facial deformity. I have seen older children with fused sutures that have undergone invasive surgical correction for positional nonstenotic plagiocephaly. This is what we are avoiding in Baby X by pursuing the DOC Band."

It does not make sense that the treatment prescribed (the DOC band) would be denied. It is not a new or experimental therapy and is an FDA approved device (attachment 4).

Lt Col XXXXX, a Pediatric Physical Therapist at Wright Patterson AFB, concurred with Dr. XXXXXX's diagnosis and we began aggressive repositioning practices in her office and at home to correct the asymmetries of his head and face and stretching exercises to resolve the torticollis. Unfortunately, our child has become too old for repositioning to be effective and he still has asymmetry that poses a health risk. Therefore, we have decided to use cranial banding therapy while he is still young enough for it to be effective. Once a verbal denial was received, we felt we had no choice but to proceed with the band and appeal the decision.

Positional plagiocephaly is a medical condition in which an infant's head becomes deformed or abnormally shaped, and may be caused by numerous factors including in utero constraint, developmental delays, and congenital muscular torticollis to name just a few. This condition results in severe rhomboid deformity of the cranio-facial skeleton that, left untreated, may result in asymmetrical growth of the jaw with malocclusion and temporomandibular joint problems, ocular asymmetry, and torticollis. The skull base is the template for the face, and thus determines the spatial relationship of the facial halves. The function of the face, i.e., the orbits, paranasal sinus and nasal area, the mandible, occlusion and temporomandibular joint regions, all require a symmetric relationship for ideal function. When asymmetry is beyond a certain threshold, as in our son's case, abnormalities of chewing, speech, temporomandibular joint problems, nasal airway and visual functions can be affected. If the skull base is left uncorrected, the eventual natural consequence of this may very well cause a functional abnormality that would require surgery later on.

We are enclosing all documentation, scientific articles, physician notes, and web sites used in our research for this appeal. We are certain, if you take the time to review the enclosed information, that this will serve to demonstrate that helmet therapy is necessary for our son's health and welfare.

It is imperative that therapy begin as soon as possible because our son is now well within the age in which this non-invasive/non-surgical approach is most effective. A delay in the initiation of helmet therapy reduces the effectiveness of treatment and may also lead to an increase in the severity of the deformity (attachment 5).

If we did not intervene, with the use of helmet therapy, there could quite possibly be permanent distortion of the head, which may lead to even more prominent facial asymmetry and accompanying ocular disturbances (resulting from actual deformation of the orbit) (reference 1).

It was evident, as far back as 1979, the benefits of early initiation of "helmet therapy." In the scientific article "Abnormal Head Shape in Infants" by Deidre Marshall, MD et al, Sterling Clarra, of the University of Washington states: "...the effectiveness of helmet therapy decreases if begun later...and if a child presents beyond a year and a half of age, it cannot be expected to completely correct the problem." There is also some evidence that positional plagiocephaly can result in chronic ear infections. The American Whole Health Library notes, "as the number of cranial strain patterns increases, so did incidence of middle ear infections" (attachment 6). Additionally, late correction of deformational positional plagiocephaly may be an obstacle to the development of normal visual function (attachment 7).

Studies have also linked plagiocephaly to the "...need for special services during the school-age years. Problems noted related to subtle problems of cerebral dysfunction, which were manifest during the school-age years, involving language disorders, learning disability, and attention deficits" (attachment 8).

The University of Michigan Health System web site clearly summarized our reasons for proceeding with helmet therapy..."Children with flattened heads from sleeping on their backs, or from pressure in the uterus, may need surgery if their condition, sometimes called plagiocephaly, is not corrected early on." The site also states, "Besides creating obvious cosmetic differences, positional head deformities can lead to face and jaw problems, even eating and breathing difficulty, later in life. And, once skull bones have hardened and fused together along interfaces called sutures, their shape and position can only be corrected by surgery" (reference 2).

Guidelines were established at the 1997 Craniosynostosis and Skull Molding Symposium as to the "best" method for the treatment of plagiocephaly. To summarize: "If repositioning is unsuccessful, or if the initial deformity is too severe, or if the child is too old for repositioning to be effective (5-6 months) orthotic management should be considered as the next logical alternative." In Resolution 119 (attachment 8), the American Medical Association addressed the problem of insurance companies and managed care organizations increasingly denying coverage for treatment of children's deformities, disfigurement and congenital defects, claiming that these services are non-functional and thus considered "cosmetic in nature" and therefore declared a non-covered disorder. It was cases just like our son's which prompted such action on the part of the AMA. A position paper, endorsed by the Plastic Surgery Section of the American Academy of Pediatrics, The American Society of Cranio-facial Surgeons, and the American Association of Pediatric Neurosurgeons (to name only a few) states that infant's with deformational plagiocephaly usually respond well to the use of "skull molding caps..."

During our initial search into the DOC Band and plagiocephaly we visited various medical center's web sites to research the treatment regimen for positional plagiocephaly. The Children's Hospital of Boston, Lucile Packard Children's Hospital- Stanford University Medical Center, The Medical College of Georgia, Penn State Pediatric Neurosurgery, to name only a few, all stated that a remolding band might be necessary for moderate to severe cases that do not see correction following a course of repositioning. Stanford's site states it best, "If the deformity is moderate to severe and a trial of re-positioning has failed, your child's physician may recommend a cranial remodeling band or helmet" (references 4, 5, 6, and 7).

While searching for insurance information in regard to plagiocephaly and the DOC Band we came across the website of one of your competitors, AETNA. Under their policy they require 6 mm of asymmetry in any one area of a child's measurement (reference 3). XXXXX was measured on 15 February 2003 by the Straight Ahead Physical Therapy Clinic (attachment 9). His cranial vault measurement showed a shocking 25 mm of asymmetry. This number is more than four times the amount required by AETNA to provide the banding. We are not talking about a slight flattening.

To put it bluntly, descriptives used in reference to Baby X's flattening included "very demonstrable" and "severe." These were quotes from a neurosurgeon and a physical therapist.

Finally, in the denial letter we received from your organization, Ms. XXXX references the Tricare/Champus Policy 6010.47-M, March 15, 2002, Chapter 7 Section 4.3 (III)(E) Orthotics. Through numerous contacts with both the DME department and Tricare Humana claims, we were informed that the DOC band was first added as an exclusion in March of 1999. We refute the fact that the DOC Band is currently an exclusion for two reasons:

1. Performing a quick search on the Internet we have located at least three families who have been covered by Tricare Humana AFTER the exclusion date.
 - a. XXXXXXXXXXXX's daughter XXXXX had TWO bands 100% covered. The first was fitted in July of 2002 and the second in September of 2002, both well after the exclusion date.
 - b. IXXXXXXXXXXXXXXXXX's son was fully covered by Tricare in late 1999.
 - c. XXXXXXXXXXXXXXXXXXXX also stated that her child had 100% coverage through Tricare in late 1999.
2. In speaking with the Claims Department for Tricare Humana we were informed that this is a covered service. We were even faxed an information sheet (attachment 2) to assist our son's Pediatrician in correctly coding the claim. The sheet that was faxed by Mrs. XXXX XXXX on 10 March 2003 clearly references the DOC Band, a procedure code, and total charges. Also noteworthy is the document's effective date in the upper right hand corner- 1 January 2000- again after the original exclusion date.

In summary, it seems obvious that this is a treatment that is medically necessary, not for cosmetic purposes, but to improve function and restore Baby X's head to a more normal shape. The documentation referred to in this letter specifically attests to the fact that lack of treatment leads to physical, developmental and psychological difficulties. We are particularly troubled by the fact that our physician, Dr. XXXXX, an approved provider, believes this treatment to be medically necessary for our son, yet Tricare has not chosen to accept this recommendation. We respectfully request that you reconsider the denial of coverage for this treatment. We believe that we have more than adequately demonstrated the medical necessity of orthotic helmet therapy for Baby X. We feel confident that the information we have provided will be of use to you in reconsidering the previous denial, and we look forward to your response.

Sincerely,

XXXX and XXXX XXXXX

CC:

Senator Mike Dewine

Senator George Voinovich

Congressman David L. Hobson

State Senator Scott Nein, Chair- Insurance, Commerce and Labor Committee, The Ohio Senate

State Senator Lynn Watchmann, Chair- Health, Human Services and Aging Committee, The Ohio Senate

Attachments:

1. Humana Military Healthcare Services Denial Letter, Dated 21 February 2003
2. Fax and Fax Cover Sheet (2 Pages inclusive), XXXXX XXXXX, Tricare Service Center, Dated 10 March 2003
3. Letter of Medical Necessity, Dr. Amy XXXXXX, Dated 22 April 2003
4. Federal Register: July 30, 1998 (Volume 63, Number 146)
5. Long-Term Developmental Outcomes in Patients with Deformational Plagiocephaly
6. Osteopathy: OMT Abstract, Cranial Dysfunction in Otitis Media
7. Ocular findings in children operated on for plagiocephaly and trigonocephaly

8. American Medical Association House of Delegates Resolution 119
9. Straight Ahead Pediatric Physical Therapy, Measurement Letter

References:

1. Graham, J. CSMC Pediatrics/Medical Genetics: Management of Plagiocephaly and Torticollis, Ahmanson Pediatric Center/ Cedars-Sinai Medical Center
2. University of Michigan Health Systems Web Site
<http://www.med.umich.edu/opm/newspage/2001/babyhelmet.htm>
3. AETNA Policy on DOC Band Treatment, <http://www.aetna.com/cpb/data/CPBA0379.html>
4. The Children's Hospital of Boston
<http://web1.tch.harvard.edu/cfapps/A2ZtopicDisplay.cfm?Topic=Deformational%20Plagiocephaly>
5. Lucile Packard Children's Hospital- Stanford University Medical Center
<http://www.lpch.org/DiseaseHealthInfo/HealthLibrary/craniofacial/dfrmplag.html>
6. The Medical College of Georgia <http://www.mcg.edu/SOM/neurosurgery/Plagio.htm>
7. Penn State Pediatric Neurosurgery
<http://www.hmc.psu.edu/pediatricneurosurgery/services/helmet.htm>