# UNITED HEALTHCARE APPEAL PACKAGE
# ON BEHALF OF BABY X

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**Your Name & Address Here**
**July 24, 2003**

**United Health Group Appeals**
**P O Box 659773**
**San Antonio, TX 78265**

**Re:** **Baby X**
**ID:** **Member # xxx-xx-xxxx**
**Group XXXXXX**

Dear Sir or Madam:

We are responding to the letter from Adrian Monroe, UHC Care Coordination, dated July 9, 2003, in which United Healthcare (UHC) denies coverage for STARband therapy for our daughter, XXXXX. Your denial letter states the following reason as the basis for your denial of benefits: "Specific orthotics exclusion".

While your letter made no attempt to further explain your reasons for denial, the attached supporting documentation will clearly show that the exclusion cited is in direct contradiction to AMA Policy H-185.967 on *Coverage of Children's Deformities, Disfigurement and Congenital Defects.*

We are at a loss to understand this decision, as all the medical advice and documentation points to this as medically necessary. We, respectfully, challenge your assertion and would like for you to review the following information:

1. Examination of Exclusion G
2. Faulty underlying assumptions in UHC's Coverage Statement on Cranial Remolding Devices
3. My daughter's diagnosis of "severe" deformational positional plagiocephaly
4. Current standards of care use in treating patients with plagiocephaly

Thank you for your time regarding this matter.

Sincerely,

Name Here

*Enclosures*

***Sent July 24, 2003 via Certified Mail with Return Receipt Requested***

**IMPLIED MEANING / CONTEXT OF EXCLUSION**
The exclusion you cite in the denial letter is taken from the following in the United Healthcare Select EPO Benefit Summary (form SCHPO002, dated 9/23/2002)[1] :

> "G. Medical Supplies and Appliances: Devices used specifically as safety items or to affect performance primarily in sports related activities. Prescribed or non-prescribed medical supplies and disposable supplies including but not limited to elastic stockings, ace bandages, gauze and dressings, syringes and diabetic test strips. Orthotic appliances that straighten or re-shape a body part (including some types of braces). Tubings and masks are not covered except when used with Durable Medical Equipment as described in your SPD."

Despite UHC's inability or unwillingness to provide us with a complete certificate of coverage and definitions of all applicable medical terminology, we feel that you must examine the **context and implied meaning** of this exclusion to determine the true intent and application Because UHC has not furnished me with such information, I have cited the definitions of two other major insurance organizations, Aetna and Cigna, below for your reference.

The band will be used to treat an abnormal structure in our daughter (her skull) and to improve function. As you are aware, if left untreated, deformational plagiocephaly can lead to a number of medical problems including but not limited to respiratory and vision problems, migraines, difficulty chewing, TMJ and sinus complications. For these reasons, it is apparent that the device is not being used simply to "reshape" a body structure into a more desirable appearance.

Again, the band is not to "re-shape" a body part. In fact, it is to "reconstruct" an abnormal head in accordance with the AMA's definition.

The cranial remolding device is **NOT:**
- A sports related device
- A safety item
- A medical supply
- A disposable supply
- Available at any local drug store (unlike the gauzes, bandages, and dressings cited in the exclusion clause)
- An orthotic prescribed for the primary purpose of "reshaping" a body part
- A cosmetic service

The cranial remolding device does, however, meet the definition of Durable Medical Equipment and has, in fact, been covered by many insurance carriers as such, including United Healthcare! In fact, we were advised on 6/19/03 by a UHC representative that the band was covered under DME.

*Durable Medical Equipment as defined on CIGNA's website*[2]:
"Equipment that can withstand repeated use and is primarily and usually used to serve a medical purpose, is generally not useful to a person in the absence of illness or injury, and is appropriate for use in the home."

*Durable Medical Equipment – Aetna's policy as found on their website*[3]:

"Aetna covers the use of a cranial remodeling band as durable medical equipment for moderate to severe positional head deformities associated with premature birth, restrictive intrauterine positioning, cervical

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[1] Refer to enclosed <Your Company's Name>. Select EPO Benefit Summary dated 9/23/02.
[2] See CIGNA guidelines for DME, printed from the CIGNA website. July 2003.

[3] See Aetna guidelines for remolding bands covered as DME, printed from the Aetna website. July 2003.

abnormalities, birth trauma, torticollis (shortening of the sternocleidomastoid muscle) and sleeping positions in children after 4 months and before 18 months of age…"

**Based on this, we feel that UHC has improperly classified the cranial band as a medical supply and, therefore, applied an exclusion in order to deny coverage. We feel it should correctly be considered DME and covered at 100%, as outlined in the Benefits Summary. Additionally, we urge UHC to conform, in both policy and application, to the guidelines set forth by the AMA.**

FAULTY UNDERLYING ASSUMPTIONS IN UHC'S COVERAGE STATEMENT

On 7/8/03, <Mother's name>contacted UHC and was told by the representative that there was no additional literature that could be mailed to support your denial. Despite this, XXX was able to find the Coverage Statement on myuhc.com. Portions of that statement have been cited below.

> UHC Coverage statement[4]:
>
> Cranial orthotic devices are a covered health service in infants with severe prenatal non-synostotic plagiocephaly. These devices are not a covered health services in infants with mild to moderate prenatal plagiocephaly or infants with post natal positional deformities due to the lack of evidence that such infants are at risk for ocular or oral functional impairments.
>
> Clinical considerations:
> Physician must provide information that infant falls into a high risk group and that functional impairment such as ocular or oral dysfunction may occur later because of the persistence of the severe plagiocephaly.
>
> Benefit considerations:
> In the absence of severe plagiocephaly, use of a cranial orthotic device to improve head shape is cosmetic and it not a covered service.

The cranial remolding band should be considered to be for reconstructive rather than reshaping purposes and, therefore, the exclusion you cite as your basis for denial is not applicable. The assertion in your coverage statement that the device is cosmetic is simply false. In fact, Dorland's Medical Dictionary defines orthosis as follows: "An orthopedic appliance or apparatus used to support, prevent, or correct deformities or to improve the function of moveable parts of the body."

Additionally, your coverage statement claims there is no documented significant impairment. However, there is ample evidence to support our claim of long-term effects due to untreated plagiocephaly. Please refer to the following enclosed material, which should be adequate to prove your claim is incorrect[5]:

> "Mandibular dysmorphology in unicoronal synostosis and plagiocephaly without synostosis", Kanre, Vannier and Marsh. September 1996.
> "Ocular findings in children operated on for plagiocephaly and trigonocephaly", Genitori and Conrath, November 1996.
> "Long Term Developmental Outcomes in Patients with Deformational Plagiocephaly", Miller and Clarren, February 2000.

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[4] See the UHC Coverage Statement for Cranial Remolding Therapy. Printed from the myuhc.com website. July 2003

[5] Recent medical literature supporting claim that untreated plagiocephaly can result in adverse long-term health implications. See attachments for articles.

More importantly, UHC's Coverage Statement is in complete disagreement with published policy of the American Medical Association (AMA). **AMA Policy H-185.967** on *Coverage of Children's Deformities, Disfigurement and Congenital Defects* states[6]:

> The AMA declares: (1) that treatment of a minor child's congenital or developmental deformity or disorder due to trauma or malignant disease should be covered by all insurers; (2) that such coverage shall include treatment which, in the opinion of the treating physician, is medically necessary to return the patient to a more normal appearance (even if the procedure does not materially affect the function of the body part being treated); and (3) that such insurability should be portable, i.e., not denied as a pre-existing condition if the patient's insurance coverage changes before treatment has been either initiated or completed. (Sub. Res. 119, I-97)

In addition, **Resolution 119** (I-97) that provides more detailed comments from the House of Delegates about Policy H-185.967 states "…Twelve states have passed legislation requiring insurance coverage for children's deformities or craniofacial surgery; therefore be it… RESOLVED, That the AMA seek legislation to achieve this objective.[7]"

I have enclosed an example of recent state legislation which indicates a trend toward requiring coverage for craniofacial disorders. Connecticut Public Act No 03-37 states that policies renewed or continued in this state on or after October 1, 2003, shall provide coverage for medically necessary orthodontic processes and applicances for the treatment of craniofacial disorders for individuals eighteen years of age or younger…" [8]

Most importantly, **AMA Policy H-475.992[9]** on *Definitions of "Cosmetic" and "Reconstructive" Surgery* states:

> (1) Our AMA supports the following definitions of "cosmetic" and "reconstructive" surgery: **Cosmetic** surgery is performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem. **Reconstructive** surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance.
>
> (2) Our AMA encourages third-party payors to use these definitions in determining services eligible for coverage under the plans they offer or administer. (CMS Rep. F, A-89; Reaffirmed: Sunset Report, A-00)

Additionally, the STARband has obtained FDA clearance as a "functional orthotic". According to the FDA:

> "The device is assigned the generic name "cranial orthoses" and it is identified as a device intended for use 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 also stated that this condition is a functional problem and not cosmetic. In order to receive FDA approval, sufficient research and evidence had to be shown. We assume the medical directors and

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[6] **See Policy H-185.967** on *Coverage of Children's Deformities, Disfigurement and Congenital Defects*

[7] See Resolution 119.

[8] See Public Act No 03-37, "An act requiring health insurance coverage for craniofacial disorders"

[9] See AMA Policy H-475.992[9] **on *Definitions of "Cosmetic" and "Reconstructive" Surgery***

reviewing physicians within the UHC organization are members of the AMA and would rely on the same guidelines set by the AMA and FDA when making decisions regarding benefits for our daughter.

**Clearly, United Healthcare's opinion that non-synostotic plagiocephaly is cosmetic in nature and that there is no evidence to support the claim of future health implications is without foundation in the medical community. The tens of thousands of doctors that belong to the AMA believe otherwise. Additionally, your position of denying treatment for a child's congenital deformity is in contradiction to guidance from the AMA. In fact, AMA Policy H-185-967 goes even further: it states that all insurers are to provide coverage for a minor child's congenital or development deformity EVEN if for appearance purposes only.**

**Again, we urge UHC to conform, in both policy and application, to the guidelines set forth by the AMA. Additionally, the American Academy of Pediatrics recently issued a clinical report which states the following:**

> "The best response for helmets occurs in the age range of 4 to 12 months because of the greater malleability of the young infant skull bone and the normalizing effect of the rapid growth of the brain…The use of helmets and other related devices seems to be beneficial primarily when there has been a lack of response to mechanical adjustments and exercises."[10]

DIAGNOSIS OF SEVERE PLAGIOCEPHALY, CURRENT STANDARDS AND RESEARCH

In Dr. Reisner's July 14, 2003 letter[11] to UnitedHealthcare he states that Baby X "has been diagnosed with severe occipital plagiocephaly. This congential deformity consists of occipital flattening right more than left with corresponding forward rotation of the ear and bowing of the forehead." The letter goes on to "recommend Baby X be placed in a cranial band".

It should be noted that Dr. Andrew Reisner is Board Certified in Pediatric Neurological Surgery. Dr. Reisner's services are covered under the UnitedHealthcare Provider Network. He is listed and recognized as a specialist in the field of pediatric neurosurgery by UnitedHealthcare in their UnitedHealthcare Physician and Provider Directory. Because of this recognition by UnitedHealthcare, under no circumstances can UnitedHealthcare not consider the statement of Dr. Reisner as expert opinion.

In addition, you should note that XXXXX, Baby X's mother, was diagnosed by Dr. Thomas Sharon during the early stages of pregnancy as being ANA positive (Antinuclear antibody)[12]. As you might not be aware, the mother was prescribed aspirin therapy and monitored by non-stress tests performed twice weekly at her OB-Gyn's office beginning in week 32 of pregnancy. These tests were necessary to monitor fetal movement. On at least one occasion, the mother was referred to Northside Hospital for additional ultrasound monitoring to ensure the health of the fetus.

As you know, recent literature suggests that most skull deformities present at birth are the result of in utero or intrapartum molding. In a December 2002 study published by W. Peitsch, MD et al, the authors explain futher:

> "Cranial flattening is more frequently observed on the right side. In our study, right-sided flattening was present in 54%, left sided only in 41%, corresponding to observations in infants with deformational plagiocephaly. One possible reason for the higher incidence of right-side flattening might be a preponderance of the left occipital anterior presentation at birth. In this position, the infant's right occiput is compressed against the maternal pelvic bone and the left

10 See "Prevention and Management of Positional Skull Deformities in Infants", AAP, July 2003.
11 Letter from Dr. Andrew Reisner to United Healthcare.
12 Select Medical Records for Mother.

> forehead against the lumbosacral spine…Thus, preponderance of right-sided flattening is not surprising”.[13]

In the absence of evidence to the contrary, UHC is in no position to conclude that this deformity is postnatal. Under the UHC policy, “cranial orthotic devices are a covered health service in infants with severe prenatal nonsynostic plagiocephaly”.

**Again, Dr. Reisner, an expert in the area, has prescribed band therapy for XXXXX. Her diagnoses meets all the criteria as outlined in your coverage statement and, therefore, coverage should not be denied.**

**SUMMARY**

Because our doctors have emphasized that this treatment was medically necessary and that time is of the essence, and despite UHC's initial refusal to cover the cost of treatment, we have proceeded with the prescribed treatment, at significant financial hardship to ourselves. Our options, as we saw them were as follows:

(1) No treatment. Given the well-documented potential for both short and long-term physical, developmental, and psychological problems, we felt this option was unacceptable. As demonstrated, early intervention is essential. Since our daughter is already 11 months old, we do not have the luxury of waiting for UHC to reconsider their opinion prior to proceeding with treatment. As you are aware, we have almost past the optimal window for treatment, usually considered to be 3 to 12 months of age.
(2) Surgical intervention. While surgery was not immediately deemed necessary, the condition could continue to worsen resulting in additional costs and risks.
(3) Cranial banding therapy. This non-invasive, pain-free procedure was by far the most logical option. Indeed, this pre-emptive therapy if covered by 90% of all insurance companies. I have enclosed a list in the appendix of this document which indicates such. We felt it imperative to proceed with this treatment while it is still an option.

In addition to requesting your reconsideration of our case, we urge you to act to educate consumers and parents of the causes, effects, and treatment of plagiocephaly. As you can see, early intervention attempts and non-invasive treatment options will help to decrease potential long-term effects to both the infant. Additionally, the insurance industry has a responsibility to provide preventative medical care for its consumers. It is in everyone's best interest and it is our hope that you use your advertising and education channels to help spread the word.

Mr. and Mrs. XXXXX

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[13] See “Incidence of Cranial Asymmetry in Healthy Newborns”, Peitsch, W. et al. December 2000.

**Baby X's Diagnosis and Course of Treatment History**

On or about XXX, 2002:

We noticed flattened area on posterior right side of Baby X's skull. We discussed this concern with Ms. Candace XXXXX, CPNP at Children's Medical Group on numerous occasions, as documented in Baby X's enclosed medical records. We were advised that the flattening would self-correct over time when Baby X gained more mobility through sitting and rolling.

Upon the pediatrician's advice as well as our own research, we attempted to intervene through the following recommended alternative treatment methods:

- Nightly alternating the supine head position during sleep
- Supervised "Tummy time" during wake periods
- Change the infant's orientation to outside activity
- Rotating feeding and diapering positions
- Use of a foam wedge positioning device during sleep periods
- Use of a front-carrier

On June 18, 2003:

On June, 2002, Dr. Andrew Reisner of Pediatric Neurogeons completed an evaluation of XXXXX's misshapen skull. Upon completion of a directed examination, Dr. Reiser diagnosed XXXXX with moderate to severe positional plagiocephaly.

Dr. Reisner prescribed a molding band and made arrangements for XXXXX to see an orthotic specialist at Children's Healthcare of Atlanta (CHA).

CHA's office informed us that we would need pre-approval for the STARBand treatment from UnitedHealthcare or we would be required to pre-pay $2000 for the treatment.

**Insurance Coverage Chain of Events**

Insert your log of events here.