

December 18th, 2001
XXX, Appeal Coordinator
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RE: Patient: XXX
Employee: XXX
ID#: XXX
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To Appeals Committee/ XXX:

BABY's Background/ CIGNA Response:

BABY's CIGNA approved Pediatric PCP, Dr. ZZZ, had referred us to see a qualified pediatric neurological surgeon, Dr. Antonio Pratts from Miami Children's Hospital. After observing BABY, his diagnosis was having: i) flat head; ii) frontal bossing; and iii) ear displacement. BABY was over 6 months old at the time of this diagnostic, was born 35 weeks gestational age and had been under a respiratory device in NICU. My son's skull deformity had been progressing in severity, despite aggressive repositioning to try and correct the very noticeable deformity. The skull sculpture of BABY prior to treatment demonstrates the severity of the deformation. The skull sculpture is being displayed today to CIGNA Appeal's Committee.

Since we had already tried aggressive repositioning, **it was suggested by Dr. Pratts that the DOC band was the best option for correcting the moderate to severe positional plagiocephaly** (Reference:1,2). If left untreated, our infant can have persistent facial asymmetry, which can affect mandibular mechanics, jaw function, airway and orbital alignment as well as possible psychological injuries. For this reason, **the DOC Band is deemed a Medical Necessity and Time is of the Essence.**

We initially received **CIGNA's denial for coverage** on September 20th, 2001. It basically stated that coverage is not available for the requested benefit because the **treatment does not currently meet CIGNA's established criteria for improved health outcomes, implying that condition is cosmetic.** After appealing (Reference:2,3), CIGNA sent another letter indicating:

The use of cranial bands and soft-shell helmets for the correction of plagiocephaly without synostosis (PWS) has been reviewed extensively by the Technology Evaluation Center (TEC), an independent technology review board of specialists, and by the Technology Assessment Council for CIGNA HealthCare, Inc. Each new technological treatment procedure or device is assessed against five criteria:

1. The technology must have final approval from the appropriate government regulatory bodies;
Criterion Met: This is an FDA approved device. FDA confirms it is not investigational.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
Criterion Met: It is demonstrated in this letter and references that there is scientific evidence (studies) related to positive health outcomes of cranial orthosis.
3. The technology must improve the net health outcome;
Criterion Met: Again, studies have clearly demonstrated positive health outcomes, as demonstrated in this letter.
4. The technology must be as beneficial as any established alternative; and
Criterion Met: Yes, there is NO established alternative treatment that has a more beneficial effect, neither in-network nor out-of-network.

5. The improvement must be attainable outside of the investigational setting.

Criterion Met: Yes, this letter and related demonstrates that this treatment provides a clear improvement. This treatment is not experimental nor investigational.

The TEC conclusion was that "cranial orthosis for plagiocephaly without synostosis does not meet the TEC criteria". The CIGNA Technology Assessment Council reviewed these findings on May 9, 2000, and agreed with the TEC conclusions. This treatment was considered unproven and therefore "experimental/investigational". **We are at a loss to understand why CIGNA's initial assessment.**

Our appeal is based on the following considerations:

1. Improved Healthcomes: DOC treatment is not Cosmetic: AMA Declarations & FDA Approval:

According to the American Medical Association's Resolution 119 on Coverage of Children's Deformation, Disfigurement and Congenital Defects, the AMA is aware of insurance companies and HMO's denying benefits for treatments of craniofacial deformities, disfigurements and congenital defects because the companies claim these problems are non-functional and thus considered "cosmetic" in nature and therefore are a non-covered disorder. This resolution plainly states that "**children who do not have birth defects and facial anomalies repaired face long term physical and psychological injuries...**" AMA policy goes on to state "**Cosmetic surgery (therapy) is performed to reshape Normal structures of the body in order to improve the patient's appearance and self-esteem. Reconstructive surgeries (therapies) are performed on Abnormal structures of the body, caused by congenital defects, developmental deformities...are performed to Improve Function.**" (Reference:4)

The DOC Band prescribed by Dr. Pratts is an FDA approved device. FDA confirms that it is not an investigational device. The FDA has also said that this condition is a functional and not cosmetic problem. We assume that the physicians reviewing this appeal for CIGNA are **members of the AMA and would not recommend action contrary to AMA and FDA standards.**

2. Long-Term Effects due to untreated deformational plagiocephaly:

There is ample evidence to support long-term physical effects due to untreated deformational plagiocephaly.

- At the 38th annual AOA conference, B.F. Degenhardt, D.O., *et al.* presented findings regarding the relationship of head shape to otitis media. They observed, "**those children who had plagiocephaly...had an increased risk of middle ear infections. Additionally, non-treated positional plagiocephaly has been linked to migraine headaches, difficulty chewing, TMJ and respiratory and vision problems.**" (Reference:7)
- R.I. Miller and S.K. Clarren, in a paper published in the journal *Pediatrics*, examined links between developmental delay and deformational plagiocephaly and concluded that "**infants with deformational plagiocephaly comprise a high-risk group for developmental difficulties presenting as subtle problems of cerebral dysfunction during the school-age years.**" (Reference:17)
- John Persing, M.D., chief of Plastic Surgery at Yale University medical Center, says that a flat head can "single out a child for unwanted problems later on that could be due to physical distortions in the face as well as the skull. That's because when you have a flattening in the back of the skull, it often has facial effects not only in the cheekbones but in the jaw. If there's enough of a distortion, kids can pick up on that and, particularly around 5 or 6 years of age, it can be a real problem for children in terms of being accepted within their intended peer group, in how they socialize and even how they do in school." (Reference:16)

As parents, we are unwilling to allow such physical, developmental and psychological problems to arise when a non-invasive treatment is available to help prevent and correct them.

3. Proven Technology with Several Studies:

It was evident, as far back as 1979, the benefits of early initiation of “helmet therapy.” Recent studies continue to demonstrate its effectiveness.

- In the scientific article “Abnormal Head Shape in Infants” by Deirdre Marshall, MD et al, Sterling Clarren, 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”. (Reference:15)
- In the article from the Vanderbilt University Medical Center (VUMC) Reporter, “Cranio-facial Surgery Program Restores Health of Children with Severe Skull Malformations” B. Cramer of the VUMC writes “...if left untreated (plagiocephaly) the deformity can have a serious impact on the child’s growth...Because a child’s skull is formed almost 95% to its maximum by age 2, it is desirable to correct the defects early. The deformity may also cause psychological problems by the time the child is 3 or 4 years old...”. (Reference:5)
- There is also some evidence that positional plagiocephaly can result in chronic ear infections. The American Whole Health Library notes that “as the number of cranial strain patterns increases, so did incidence of middle ear infections.” (Reference:6)
- Additionally, non-treated deformational positional plagiocephaly has been linked to respiratory and vision problems, migraine headaches, difficulty chewing and TMJ (temporomandibular joint) syndrome. (Reference:18) Finally, to put it simply, **Early recognition and treatment are essential in obtaining an optimum clinical outcome .**
- 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!”. (Reference:13)
- A position paper, endorsed by the Section Plastic Surgery 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...”. (Reference:15)
- Dr. Ann Flannery, Department of Surgery/Section of Neuro-Surgery at the Medical College of Georgia states: “...Babies who are severely effected can also be placed in a molding helmet or band...”. (Reference:9)
- However, Cedars-Sinai Medical Center, Department of Pediatrics position on the management of plagiocephaly and Torticollis states it best: “...Management for infants who do not make progress with exercise alone, or for infants with moderate to severe plagiocephaly still present at 6 months involves use of a corrective helmet...the results have been excellent...”. (Reference:10)
- As noted by Dr. Deirdre Marshall, of the Miami Children’s Hospital, **“Insurance companies and HMO’s must realize that prompt authorization of requests for helmet therapy in children requiring them will, in the long run, be much more cost effective than denying or postponing authorization for a helmet and then having to fund a major intracranial surgical procedure...”** (Reference:15)

4. DOC Band Therapy Effectiveness:

Cranial banding therapy (DOC Band therapy) is **Very Effective** in the treatment of positional deformational plagiocephaly/ brachycephaly (See Reference 3 for more details). Many research articles have reached this significant conclusion. Research summaries show:

1. Documented statistically significant increase in cranial growth.
2. Reduction of cranial asymmetries.
3. Infants treated with banding therapy exhibit growth trajectories similar to normal.

In other words, DOC Band therapy is effective in achieving complete or near-complete correction of nonsynostotic plagiocephalic characteristics.

Helmet therapy, also known as Dynamic Orthotic Cranioplasty (DOC) is classified by the FDA as a “functional orthotic” device. It has been documented to effectively replace surgery for correction of deformational plagiocephaly at a **Fraction Of The Cost**. (Reference:8,14,20)

The DOC Band is considered Durable Medical Equipment and was the first band of its type to achieve FDA approval for plagiocephaly treatment. It meets all the requirements for Durable Medical Equipment as outlined in my coverage booklet from CIGNA.

5. Options for BABY:

Because our doctor (both PCP and Neurological Surgeon) recommended this treatment (and emphasized that we should begin quickly in order to preserve the chance for the best outcome) and despite CIGNA’s initial refusal to cover the cost of BABY’s DOC band treatment, **we have proceeded with the prescribed treatment at significant financial hardship to ourselves**. Our options, as we saw them, were as follows:

A) No treatment. Given the fact that BABY already has an uphill struggle ahead of him, we thought it would be entirely foolish and unacceptable to further complicate his life by exposing him to well-documented psychological, physical and developmental problems due to his plagiocephaly. We had already done extensive physical repositioning. Further, as **BABY was 7 months old, we did not have the luxury of waiting to see if his condition would worsen** to the point where CIGNA would deem the helmet medically necessary or to postpone treatment while your decision was on appeal. Time was of the essence.

B) Surgical Intervention. While surgery was not immediately deemed necessary, had BABY’s condition continued to worsen, it may well have been required. The cost of surgery could easily exceed twenty times the cost of the DOC helmet. This helmet is a *functional orthotic*. Almost all carriers have underwriting for a *functional orthotic* because the replacement treatment is usually as effective at a **fraction of the cost**. (Reference:8,14,20) Risks due to surgery are obvious and we had no desire to put our son through a great deal of pain and suffering when a less expensive, equally effective, non-invasive option existed.

C) FDA approved Cranial Technologies DOC Band helmet. This non-invasive, relatively inexpensive, pain free procedure was by far the best option. Given that we diligently performed physical therapy and repositioning without correction, the helmet was the next logical step.

6. CIGNA and other Insurances have paid for DOC Band in the past.

CIGNA plan has paid for DOC band helmets for patients with diagnoses identical to my son. Additionally, most insurance carriers have in their underwriting, coverage for functional orthotics and approximately 95% of all insurance carriers approve and cover the cost of the DOC Band Treatment. Through extensive research, we have found that the following partial list of a few of the insurance carriers that have approved and paid for the DOC Band Treatment:

- Aetna,
- American Community,
- American Family Insurance Group,
- Anthem Blue of Indiana,
- Blue Cross Blue Shield of AZ and TX and CA,
- Champus and Partners Health Plan,
- **CIGNA**,
- Corporate Health Administrators,
- First Health,
- Gem Insurance,
- Health Partners Plan,
- Humana,
- Intergroup,
- Kaiser,
- Motorola, FHP, EDS, and Principal.
- Prudential,
- State AHCCS of Arizona,
- Texas Medicaide,
- Tri Care,
- Unicare,
- United HealthCare

ZZZ (our employer) had selected CIGNA as a Healthcare partner for its employees because of the quality of services rendered.

Since CIGNA has paid for the DOC Band in the past, our claim should not be denied. This can be considered being Prejudice towards BABY.

7. Insurance Commissioner Findings:

In a recent case, IPRO, the agency that handles external appeals for **the Insurance Commissioner, reversed an Insurer's decision to deny coverage** for an FDA approved helmet as treatment for positional plagiocephaly. In this case, the infant had plagiocephaly, as does BABY.

The **Insurance Commissioner's finding** is important. Referring to the helmet, the reviewer writes:

“ This device is not used for **Cosmetic** purposes, but rather for **Reconstruction**. Cosmetic surgery is defined as surgery used to reshape normal structures of the body...to improve a patient's appearance. This patient had a deformity of the skull caused by head position. If left untreated, the ears can also move into abnormal positions. This baby's head was not normal. This is clearly not cosmetic treatment and should be considered a covered benefit. Please see Neurosurgery Focus 9 (3), May 2000. This device is the preferred method of treating positional plagiocephaly after repositioning and physical therapy have failed. **This is the standard of care for this disorder. Therefore, the decision to deny coverage for a dynamic orthotic cranioplasty band should be reversed.**”

(Reference:11)

Conclusion:

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'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. Pratts, a approved provider and an expert in this field believes this treatment to be necessary for our son, yet CIGNA 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 necessity of DOC Banding therapy as well as its improved health outcome. FDA approved the DOC band and clearly states that it is not an investigational device/ treatment. Several studies clearly demonstrate this as well. 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.

We are requesting retroactive coverage for DOC Band therapy and reimbursement from CIGNA for \$3000.00 under our Durable Medical Equipment coverage. We are aware that CIGNA have covered DOC Band treatment, and we are requesting the same standard of care for our son.

Thank you for your time regarding this matter.

Sincerely,

XXX
(parents to BABY)

CC: Antonio Pratts, M.D., Pediatric Neurological Surgeon, Miami Children's Hospital
ZZZ, M.D., CIGNA approved Pediatric PCP
Tom Gallagher, Commissioner of Insurance, State of Florida
ZZZ, Employee Benefits Director, (my company)
Fatima Miranda, Cranial Technologies
JEB Bush, Governor of Florida
Jessie Helms, Senator

Enclosures: (20 References, 3 Letters from Neurosurgeon, 1 Letter from Cranial Tech to CIGNA demonstrating device is not 'experimental/ investigational, IPR0 Insurance Commissioner Findings Letter)

References:

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2. Dr. Antonio Pratts, Letter to CIGNA, dated September 25, 2001.
Dr. Antonio Pratts, Letter to CIGNA, dated November 29, 2001.
3. Tim Littlefield from CT, Extensive Letter to CIGNA related to BABY, dated October 31, 2001.
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 - a. American Society Of Plastic And Reconstructive Surgeons
 - b. American Society Of Maxillofacial Surgeons
 - c. American Association Of Plastic Surgeons
 - d. American Academy Of Child And Adolescent Psychiatry
 - e. American College Of Surgeons
 - f. American Pediatric Surgical Association
 - g. American Society For Surgery Of The Hand
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12. Kelly, K., Et Al., Importance Of Early Recognition And Treatment Of Deformational Plagiocephaly With Orthotic Cranioplasty, *Cleft Palate Craniofacial Journal*, 1999; 36: 127-130.
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16. Melville, Nancy, Baby Molds: Shape Of Their Future Starts With Their Heads, *Health Scout News*, August 19, 2001. [Http://Www.Safetyalerts.Com/T/Hs/Molds.Htm](http://www.Safetyalerts.Com/T/Hs/Molds.Htm)
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18. Plagiocephaly, Ask Dr. Stoll, [Http://Bcn.Net/~Stoll/Plagio.Html](http://Bcn.Net/~Stoll/Plagio.Html)
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