Dear XXXX,

I am responding to the letter I received in January of 2002 denying medical benefits for my daughter’s cranial molding helmet. When inquiring as to the reason for this denial, it was communicated to me by both XXXX XXXXX and yourself that the lack of objective evidence supporting functional problems was the basis for the denying coverage of the $1600 cost of the device. Per your request, I have included several documents, which will provide the data that you requested.

This appeal is organized according to the following enclosures:
1. **Diagnosis of Baby X’s condition** by Dr. XXXX XXXX, M.D.
2. **X-ray report** from St. Vincent hospital confirming diagnosis.
3. Article on **Mandibular dysmorphology in unicoronal synostosis and plagiocephaly without synostosis**.
4. Article on Long-term **developmental outcomes in patients with deformational plagiocephaly**.
5. Article on **Cranial dysfunction in Otitis Media**.
6. Article on Cranio-facial surgery program restores health of children with severe skull malformations.
7. Photo of Baby X’s head prior to treatment (Jan 17, 2002)
8. Photo of Baby X’s head after 7 weeks of treatment (March 2, 2002)

**Enclosure #1 - Diagnosis of Baby X’s condition by Dr. XXXX XXXX, M.D.**

As was included with my original claim, a letter from Dr. XXXX XXXX, M.D. is attached with his diagnosis of posterior plagiocephaly. Plagiocephaly (Play-gee-oh-sef-aly) is also referred to as “Flat Head Syndrome”. As you will see from an attached photo, Baby X had border line severe flattening on her right side. At her two month check up, her pediatrician recommended repositioning techniques to relieve the pressure from her flat spot. We tried this for eight weeks with no success. At her four month check up, Dr. XXXX XXXX, Baby X’s pediatrician recommended more aggressive treatment. We were told by Dr. XXXX that flattening as severe as Baby X’s was unlikely to resolve itself on its own and he referred us to Dr. XXXX. In early January, we visited Dr. XXXX who is a cranial facial specialist and certified surgeon. This is when we received the diagnosis. Through a variety of researches, I determined that timing was critical to get optimal results with cranial molding therapy. We moved ahead and within two weeks she received her helmet.
Enclosure #2 - X-ray report from St. Vincent hospital confirming diagnosis.
After the initial denial of our claim, it was suggested to me by XXXX XXXX that we obtain some objective testing data confirming Baby X’s diagnosis. It was the recommendation of our specialist, Dr. XXXX, that CT scans would be too extreme for this diagnosis. Not only are the CT scans very expensive, but Baby X would have to be anesthetized. Dr. XXXX felt strongly that it was not necessary to put our daughter at risk, so he recommended skull x-rays. The X-rays were taken on January 15, 2002 and a copy of the report is included. As you can see from the report, Baby X’s x-rays are in line with those of plagiocephalic infants. Her sutures appear normal which is also a trait of plagiocephaly. The fact that the sutures are open rules out the possibility that Baby X’s condition is a result of synostosis, thankfully giving us other options besides surgery for treatment.

Enclosure #3 - Article on Mandibular dysmorphology in unicoronal synostosis and plagiocephaly without synostosis
A study at the Washington University School of Medicine in St. Louis, Missouri, reports that patients with plagiocephaly without synostosis have distinctive skull dysmorphologies. The study proves that the hypothesized presence of diagnosis specific mandibular dysmorphology in plagiocephaly without synostosis is confirmed. This is proven with statistical significance utilizing a common statistical technique (the t test).

Enclosure #4 - Article on Long-term developmental outcomes in patients with deformational plagiocephaly
A study conducted at the Center for Human Development and Disability at the University of Washington School of Medicine, in Seattle, Washington, determined that infants with deformational plagiocephaly comprise a high-risk group for developmental difficulties. These difficulties can require the need for special education assistance, physical therapy, occupational therapy, and speech therapy, just to name a few of the possibilities.

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.” (Pediatrics 105: E26, February 2000).

Enclosure #5 - Article on Cranial dysfunction in Otitis Media.
There is ample evidence to support the claim of 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 that “Those children who had plagiocephaly...had an increased incidence of middle ear infections.” Additionally, non-treated positional plagiocephaly has been linked to migraine headaches, difficulty chewing, TMJ and respiratory and vision problems. It is perhaps worth noting that Baby X has suffered from a chronic ear infection since December, requiring four different
antibiotics. So far, she still has the ear infections and is due to be checked again on Monday, March 25. She has been treated with Amoxil on two occasions, Augmentin, Omnicef, and Zithromax each one time. Along with the enclosed article, I have enclosed two office visit sheets confirming the diagnosis of otitis media on Jan 29, 2002 and Feb. 28, 2002. An additional diagnosis sheet from December is also available if needed. In addition, Baby X suffers from a lazy eye on the side of the flattening. I have also enclosed the office visit sheet from her visit to pediatric ophthalmologist, Dr. XXX X XXXX. The sheet indicates the diagnosis of Intermittant Extropia.

Enclosure #6 - Article on Cranio-facial surgery program restores health of children with severe skull malformations.

In addition to restoration of physical function, the AMA recognizes that “children who do not have birth defects and facial anomalies repaired face long term physical and psychological injuries”. This is also addressed in the article “Craniofacial Surgery Program Restores Health of Children with Severe Skull Malformations” by B. Cramer. Regarding abnormally shaped skulls, Cramer says, “If left untreated, 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.” As parents, we are unwilling to allow such physical, developmental and psychological problems to arise when a non-invasive treatment is available to prevent them.

9. Enclosure #7/8 - Photo of Baby X’s head prior to treatment (Jan 17, 2002)  
Photo of Baby X’s head after 7 weeks of treatment (March 2, 2002)

I think you will agree that the photos speak for themselves. Until the cranial molding therapy became available, cranial vault reconstruction was the only treatment for this condition. The molding helmet therapy is extremely effective, especially when done at an early age. In addition, the $1600 cost is insignificant compared to the cost of surgery.

Conclusion

Because our doctor emphasized that this treatment was medically necessary, and despite Eli Lilly’s initial refusal to cover the cost of the cranial molding therapy, we have proceeded with the prescribed treatment. Our options, as we saw them, were as follows:

a. No treatment. Given the well-documented potential for short and long-term physical, developmental, and psychological problems, we felt that this option was unacceptable. As has been demonstrated, early intervention is essential to successfully correct the deformity. We had neither the luxury of waiting to see if our daughter’s condition worsened to the point where Lilly would actually deem treatment medically necessary nor did we feel we could postpone treatment while we appealed Lilly’s decision to deny coverage, since our daughter was already four months old and at the optimal age for excellent results with therapy.

b. Surgical intervention. While surgery was not immediately deemed necessary, had Baby X’s condition continued to worsen, it may well have been required. The cost of surgery can be ten to twenty times the cost of the helmet therapy. Risks due to surgery are obvious, and we had no
desire to put our daughter through a great deal of pain and physical suffering when a less expensive, non-invasive option existed.

c. **Cranial molding therapy.** This non-invasive, relatively inexpensive, pain-free procedure was by far the best option. Indeed, this therapy is covered by 90% of insurance companies according to statistics available on the www.plagiocephaly.org website. At a minimum, insurance companies are recognizing the validity to at least cover the helmet under durable medical equipment. Many more are opting to fully cover the treatment as it has become more understood.

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. The functional problems that Baby X is already suffering from (otitis media and intermittent extropia) are likely not coincidence and are related to her plagiocephaly. I hope you will agree that significant medical expenses will be avoided in the future by our decision to treat this deformation aggressively.

In closing, **I respectfully request that you reconsider the denial of coverage for this treatment.** I believe that I have more than adequately demonstrated the medical necessity of the cranial molding therapy for Baby X. I feel confident that the information I have provided will be of use to you in reconsidering the previous denial, and I look forward to your response.

Thank you for your time regarding this matter.

Sincerely,

Your Name