

Appeal  
April 2, 2001

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Douglas Beck  
Compliance Officer  
Department of Consumer and Business Services Insurance Division  
Consumer Protection 350 Winter Street NE,  
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Salem, OR 97301-3883

Re: File No. 301827-DB, Ms. Nancy Roberts

Dear Mr. Beck,

Thank you for your timely response to our inquiry. We understand that the facts provided by BlueCross BlueShield make it difficult to alter their position regarding the contractual agreement for exclusions from coverage. However, there are several documents that are relevant to specific portions of the Experimental or Investigational Services section of the contract that seem to have been overlooked in the recent review by the Regence BCBSO medical directors on March 15, 2001.

Two indicators were cited on page one of the letter your received from Dr. Donald Thieman, Vice President and Medical Director at BCBS. The letter states that these indicators show that uterine artery embolization (UAE) is in research status and therefore excluded from coverage.

The first indicator is the existence of peer reviewed articles that indicate the need for further research. Although there are cited articles from earlier years that fit this descriptions, published literature from this year indicate that UAE "is a proven method for treatment of myomata [uterine fibroids]" (Appendix A, attached). A second peer reviewed article indicates that UAE "seems to have lower morbidity and mortality, shorter hospitalization and recovery time, and is cheaper compared to surgery" (Appendix B, attached). Neither of these articles call for further research to substantiate their findings, and each provides statistical analyses of clinical trials supporting their conclusions.

The second indicator is an acceptance of the practice by a "federal governmental agency or national professional medical (or dental) society." In the Training Standards for Physicians Performing Uterine Artery Embolization for Leiomyomata (Appendix C, attached) by the Society of Cardiovascular & Interventional Radiology (SCVIR) it is stated that "clinical experience and the published literature indicate that this is an effective and safe therapy for fibroids." These training standards were developed by the Task Force on Uterine Artery Embolization and the Standards Division of the Society of Cardiovascular & Interventional Radiology (August 2000).

Although these indicators alone should provide the evidence for persuading Regence BCBS to change their position, we would like to comment specifically to the points made in the letter you received from Dr. Thieman:

1. Dr. Thieman states that no randomized controlled clinical trials have been made to compare UAE with surgical treatments. Although this is true, the requirement for random controlled trials is not in the contractual agreement for exclusion from coverage. Aside from the high cost and ethical considerations of such trials, the surgical treatments have not themselves been subjected to such stringent trials. Case series studies have indicated that the long term effectiveness of UAE is superior to an accepted surgical practice of myomectomy for recurrence of fibroids up to 3 years. Uterine embolization has been a practice since the 1970's to control uterine bleeding in emergency situations so that data does indeed exist for long term effects. With regards to the lack of data on the effects of UAE on fertility, the article referenced above suggests that UAE is comparable to other surgical treatment for fibroids.

2. In addition to the support of the SCVIR (Appendix C, attached) as stated above, the Royal College of Radiologists and Royal College of Obstetricians and Gynaecologists in the United Kingdom in their Clinical Recommendations on the Use of Uterine Artery Embolisation in the Management of Fibroids recommends UAE for women who might otherwise be advised surgical treatment. This support shows that UAE is becoming an internationally acceptable treatment for uterine fibroids.

3. Although the May 2000 document from the American College of Obstetrics and Gynecology indicated a reluctance to the procedure, it should be noted that the society is for medical professionals that are typically not trained to perform UAE and would refer patients to an interventional radiologist for treatment.

4. The expert panel funded by the CIRREF formed the committee in order to design an experiment for random clinical studies. The objective of the panel stated in the RAND technical report was to review the literature and develop a research agenda for future studies on UAE compared with other treatments for uterine fibroids. No statistical analysis was made showing that presently available data was inconclusive as to the effectiveness and safety of UAE.

The random controlled clinical trial designed by committee was proposed to NIH (grant applications R01 HD38374-01 and -01A1), but was not scored high enough to receive funding. The critique by the peer review panel assigned the revised version of the grant application shows that there were serious flaws in the design of the trials. One of the reviewer pointed out that compensation provided by the study to the clinical centers would not be adequate to cover the procedure. Because UAE is seldom covered by insurance policies, the patients and clinical centers randomly assigned to the procedure would have to pay for it themselves. To provide such compensation would drive the cost of the trials to extreme levels, particularly if the necessary sample size was underestimated as suspected by a second reviewer. Thus, in the present funding environment where such grant proposals must compete with proposed treatments for infectious and deadly diseases, it appears unlikely that such a study with sufficient sample size will ever take place.

It is ironic that the very fact that UAE is not covered by BCBS policies renders random controlled trials to be prohibitively expensive for federal funding.

5. Editorials, such as the one referred to (Goodwin et al., 2000) are typically not peer reviewed and thus should not be considered as scientifically accepted fact. Such articles simply reflect the opinions of the authors, and not the policy of the Society of Cardiovascular & Interventional Radiology (SCVIR). In this particular case, UAE was in fact accepted by the SCVIR as a treatment for uterine fibroids within four months of the publication of this editorial, as documented by the above mentioned Training Standards for Physicians Performing Uterine Artery Embolization for Leiomyomata (Appendix C, attached).

6. We are encouraged that BCBS continues to actively seek professional input on these issues, but our own experience with the OHSU medical staff is quite different from theirs. For instance, our interventional radiologist reports that he has sent a great deal of information to BCBS in support of UAE as a non-investigational treatment for uterine fibroids. We sent a single email request to him for information about national professional societies that have accepted UAE, and he immediately pointed us to the web site of SCVIR ([www.SCVIR.org](http://www.SCVIR.org)) where we downloaded the document that we submit to you as Appendix C. In addition, a document by the Dotter's Institute that was included with the first grievance letter states that UAE is not investigational.

In summary, we feel that the documentation that was sent to you by BCBS was incomplete with regards to considering UAE as an investigational treatment for uterine fibroids. The published literature and the policy of an important national professional society, the SCVIR, contradict BCBS's interpretation of the indicators for investigational procedures stated in the contract.

Sincerely,

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cc: Donald E. Thieman, M.D., Vice President and Medical Director, BCBS of OR