

September 10, 1997

xxxxxxxxxxxx
1008 NE 85th Terr.
Kansas City, MO 64155

Re: Letter from xxxxxx, September 4, 1997

Dear xxxxxxx,

The basis for the denial of you coverage of your compounded prescription is completely invalid. Ms. xxxxxx is misinformed about FDA regulations regarding compounded medications, and the situation needs to be addressed and clarified.

It is true that troches are not approved by the FDA. Troches are a compounded prescription, just like a compounded suppository, cream, capsule, suspension, etc. Compounded prescriptions are regulated by the individual state boards of pharmacy, in this case, the Missouri State Board of Pharmacy. In this regard, your prescription is in complete compliance with all state and federal regulations.

The FDA has not and does not approve or disapprove of compounded prescriptions. They never have. The FDA does not even have the legal jurisdiction to regulate prescriptions compounded for an individual that meet all state board of pharmacy regulations. The FDA's only responsibility is for mass-produced, commercially-marketed prescription medications.

Furthermore, if Ms. xxxxxx's assumption was valid, then Humana would not be able to provide coverage for ANY compounded medication because no compounded medication of any form is approved by the FDA. Even an FDA-approved medication that has been altered in any way from its original FDA-approved form, is no longer an FDA-approved substance. That is, even the mixing of two FDA-approved creams creates a medication that is no longer FDA approved!

Since you have coverage for compounded medications, and Humana covers compounded medications on a routine basis (as does every insurance carrier - keeping in mind most intravenous drugs in a hospital are compounded), you have been wrongly singled out and denied coverage.

In addition, your physician has already decided that this is the best option for your hormone replacement therapy. It is becoming increasingly apparent on a national

basis that many women can not tolerate the adverse effects of the synthetic and horse-urine derived hormone medications. Natural alternatives to this, as you know, are our specialty - with compounding expertise matched by only a few pharmacies across the country.

I hope this helps you separate fact and fiction. You may wish to contact Humana again to reassess your situation. In the event you are unsuccessful, I suggest you contact the Missouri Department of Insurance at 889-2381. Be sure to keep copies of all correspondence to provide the Commissioner if necessary.

Stay well,

Eric Everett, RPh, FIACP

cc: xxxxxx, Pharm. D.
Humana Health Care