

April 10, 2006

Maximus 1040
First Avenue, Suite 200
King of Prussia, PA 19406

VIA FACSIMILE AND U.S. MAIL

RE: Request for Independent Review for C
[identifying information redacted]
Part D Prescription Drug Plan: SilverScript

Dear Sir/Madam:

On behalf of my patient and Medicare Part D enrollee, C, I am requesting from you a reconsideration (i.e., an independent review) of the March 24, 2006, denial (i.e., redetermination) by SilverScript of Ambien. The unfavorable redetermination upheld the denial of coverage by SilverScript of Ms. C's prescription on March 8, 2006.

Specifically, SilverScript's denial stated as follows:

Participant's plan benefits does [sic] not allow for more than 14 tablets per 25 days for Ambien. The patient has been approved for a one time override of 20 tablets for weaning off the drug. No further quantity increases are allowed.

This denial is, in fact, a dose restriction as defined in the Medicare Part D regulations (i.e., 42 FR §423.578 (b)) and is an appealable matter based on medical necessity. This Section of the regulations provides that exceptions can be granted to dose restrictions where such dose restrictions, including the dosage form, cause a particular Part D drug not to be covered for the number of doses prescribed. SilverScript's own manuals state that an enrollee can ask for SilverScript to waive coverage restrictions or limits on drugs. Specifically, SilverScript's manuals state that for certain drugs, SilverScript limits the amount of the drug that they will cover, but that a patient can ask SilverScript to waive the limit and cover more. In this case SilverScript did not take a look at medical necessity and consider a waiver of their limit. Rather, the medical necessity rationale for my exception request to the dose limitation was not properly considered.

Copies of the unfavorable coverage determination and redetermination are attached. In addition, I have attached the form CMS-1696, Appointment of Representative, appointing me as Ms. C's representative to request an independent review.

1. Ms. C's Diagnosis and Brief Medical and Prescription History

Ms. C is 51 years old, and has been suffering from a delusional disorder, OCD, depression, and sleep problems. In the past, without appropriate medications, Ms. C required hospitalization; however, I have been able to appropriately treat

her with medication and outpatient therapy and she has been able to remain out of the hospital and in the community.

An important part of her treatment is 10 mg of Ambien HS. Ms. C was initially prescribed this dose of Ambien in August of 2002. She has medical need for this prescription. When she does not have Ambien at this dose, she cannot sleep. Without sleep, she faces the potential to have increased symptoms and psychiatric decompensation, which could result in hospitalizations. Ms. C has never had any issues with abuse, toleration, or lack of effectiveness. 10 mg is a standard adult dose as indicated on the package insert.

Ms. C is a dual eligible, receiving both Medicare and Medicaid, and until January 1, 2006, her medications (including 10 mg Ambien HS) were provided under her Medicaid coverage. Under Medicaid she had no problems getting the Ambien dose I prescribed.

2. Ms. C's Refill of Ambien Was denied by SilverScript

On March 8, 2006, I was informed by Caremark Prior Authorization that Ms. C would need prior authorization for Ambien. I called and described the facts above (i.e., that Ms. C was on Ambien and stable since 2002, it was successful and necessary part of her treatment, and there were no safety issues). Prior authorization was denied by SilverScript on March 8, because SilverScript would not allow more than 14 tablets per 25 days of Ambien. The patient was given a one time override of 20 tablets for weaning off the drug. On Ms. C's behalf, I requested a redetermination, and on March 24, 2006, I received a letter from SilverScript confirming the initial coverage determination.

3. Ms. C Should Be Provided with Refills

I disagree with SilverScript's decision to deny Ambien as I prescribed it. SilverScript has stated that it would not allow more than 14 tablets per 25 days of Ambien. While I understand that SilverScript has a dose restriction that would prohibit Ms. C from receiving the number of doses I prescribed, I believe that an exception should be granted for Ms. C under the circumstances.

SilverScript's own manuals state that an enrollee can ask for SilverScript to waive coverage restrictions or limits on drugs. SilverScript's manuals specifically state that for certain drugs, SilverScript limits the amount of the drug that they will cover, but that a patient can ask SilverScript to waive the limit and cover more. I asked SilverScript for an exception to their limit and SilverScript should have looked at medical necessity in this situation.

At 42 CFR §423.578(b)(5)(iii), the Medicare regulations state that in his/her supporting statement, a physician must show that the drug is medically necessary to treat an enrollee's disease. In a case where the physician is requesting a dose in excess of a dose restriction, the physician may prove that a dose is medically necessary by showing that the number of doses that is available under a dose restriction for the drug either (a) has been ineffective in treatment of enrollee's disease, or (b) based on clinical evidence and medical

and scientific evidence, the known and relevant physical and mental characteristics of the enrollee and the known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. There is no requirement that the physician establish medical necessity by proving both (a) and (b).

The operative criterion in Ms. C's case is criterion (a). In accordance with the regulations, as a physician seeking an exception to a dose and/or quantity limitation, I have provided oral and written supporting statements and provide such a supporting statement herein that the requested prescription drug is medically necessary because the number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition.

An exception to SilverScript's Ambien limits is medically necessary for Ms. C. Lower dose is not effective and, as stated, 10 mg is the usual dose for adults. Based on Ms. C's clinical history and treatment response, it is medically reasonable to conclude that the dose restriction in question has proven ineffective in the treatment of her disease, and an exception to the dose restriction should be granted.

Ambien at this dose is an essential and medically necessary component of the clinical treatment of Ms. C. While the dose of 10 mg HS is prescribing at a different dose than SilverScript allows, this dose is medically necessary in this case and is consistent with the doses that practicing psychiatrists use to treat patients with chronic and persistent mental illness who have had an inadequate treatment response to other medications and doses. Failure to provide the drug as I have prescribed it is substantially likely to adversely affect the health of Ms. C.

4. Conclusion

I respectfully request that Ms. C be granted an exception to SilverScript's dosage restriction in accordance with the Medicare Part D regulations and receive the medically necessary medications that she has been using to treat her condition since August of 2004.

Thank you for your time and consideration. If you have any questions or need any further information, please let me know.

Sincerely,

ED
Psychiatrist