

March 24, 2006

VIA FACSIMILE AND U.S. MAIL

Dear Sir/Madam:

On behalf of my patient and Medicare Part D enrollee, XXXX, I am appealing the unfavorable January 26, 2006, decision of the QIC (i.e., Maximus) to an Administrative Law Judge. The unfavorable decision upheld the decision of Ms. XXX's Medicare Part D prescription drug plan, Medco Health Solutions ("Medco").

Ms. XXX has asked me to be her appointed representative and has completed the attached Form CMS-1696, Appointment of Representative. Please note that (i) the enrollee's name, address, telephone number, and Medicare health insurance claim number, (ii) my name, telephone number, and address, and (iii) the appeal number listed in Maximus' unfavorable decision are set forth above. I understand that you will have access to Ms. XXX's file, but I am willing to provide any additional information that you may need to make your decision.

1. Introduction and Background.

a. Ms. XXXX's Diagnosis and Brief Medical and Prescription History.

Ms. XXXX is 55 years old, and has been suffering from chronic and persistent mental illness, schizoaffective disorder for most of her adult life. Schizoaffective disorder is a chronic and persistent mental illness, which is characterized by mood disorders, such as bipolar disorder, mania, and depression, along with the delusions, hallucinations, and thought disorganization that characterize a diagnosis of schizophrenia. In the past, without appropriate medication, Ms. XXXX 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, having social experiences, and at times, working part-time.

An important part of her treatment is 160 mg of Geodon, taken twice a day. Geodon is an atypical antipsychotic, which is indicated for the treatment of schizophrenia and acute manic or mixed episodes associated with or without psychotic features.

Ms. XXXX has tried a number of medications and has had an inadequate treatment response. She has tried the anti-psychotic medications Mellaril, Trilaton, Prolixin, and Zyprexa, but none of these medications (in the absence of the drug Geodon) had a

favorable outcome. In October of 2002, I initially prescribed Ms. XXXX 40 mg of Geodon twice daily and titrated up to 80 mg twice daily within an 18-day period.

In June of 2004, Ms. XXXXX was experiencing increased anger, thinking problems, anxiety, and stress at work. As a result, over a 4 month period, I increased her dose of Geodon to 160 mg twice daily. She has been on this dose since October of 2004 and has been stabilized with no paranoia, thought disruptions, or anger episodes since that time.

Ms. XXXX is a dual eligible, receiving both Medicare and Medicaid, and until January 1, 2006, her medications (including 160 mg Geodon twice daily) were provided under her Medicaid coverage. Under Medicaid she had no problems getting the Geodon at the dose I prescribed.

b. Ms. XXXX's Refill of Geodon Was Denied by Medco.

On January 1, 2006, XXX's drug coverage was automatically switched to Medicare, and Medco became the prescription drug plan responsible for providing her medications. On January 8, 2006, Ms. XXXX went to the local Wal-Mart pharmacy to refill her prescription for Geodon. The pharmacist informed her that prior authorization was needed and that I, the prescribing physician, should call Medco to obtain it. I called Medco on January 9, 2006, and was told that prior authorization was not necessary and to tell the pharmacy to "override it." I instructed Ms. XXXX to return to the pharmacy, but the pharmacy would still not refill the prescription for Geodon, again stating that prior authorization was necessary.

On January 11, 2006, I requested a coverage determination from Medco. In response, Medco sent me a fax, which had the following box checked: "No coverage review available." I appealed this coverage determination that very day. I did not receive a timely response to this appeal, so on January 16, 2006, I called Medco to ask about the status of the appeal. I was told that they had accidentally thrown away the appeal, but had documented receiving the appeal in the records. They asked me to resend the appeal, which I did.

On January 20, 2006, Medco sent me a letter stating that because no decision had been rendered within 72 hours, Ms. XXXX's appeal had been automatically forwarded to an independent review organization, and a decision would be made by Maximus, in King of Prussia, PA.

On January 26, 2006, Maximus sent me a letter stating that the appeal decision was unfavorable, with the explanation "Our decision is that Medco Health is not required to provide coverage for Geodon because we were unable to find documented evidence to support the use of the drug Geodon at the daily dose of 320 mg (160mg twice

daily).” On February 1, 2006, I responded to Maximus requesting that the case be reopened because I had articles/abstracts that supported the dose of Geodon that Ms. XXXX was taking. On February 9, 2006, Maximus sent me a letter rejecting my request to reopen the case. In this rejection they stated that they stood behind their initial decision and that for a drug to be covered as a Part D drug, a drug must meet the following criteria:

- It is approved by the FDA
- It is used and sold in the US
- It is used for a medically accepted indication
- It includes uses supported by one or more citations included or approved for inclusion in the American Hospital Formulary Service Drug Information, US Pharmacopoeia-Drug Information, and DRUGDEX Information System

At this time, because of the stress that Ms. XXXX has endured in her efforts to obtain her Geodon, she is starting to decompensate. For a couple of years, in addition to medication management, she was seen about once a month for outpatient therapy. Due to her current increased anxiety, she is now receiving outpatient therapy once a week. She is very fearful of the consequences of being treated without her full dose of Geodon, as she understands that it has been the reason for her stability in the past. My fear as her physician is that if she were to have a psychotic episode, she would decompensate to the point where she would require hospitalization. Unfortunately, each time she becomes psychotic and requires hospitalization, it takes her longer and longer to recover. Her full recovery from a future psychotic episode might take years.

c. Ms. XXXX Should Be Provided with Refills.

Aside from the issues I set forth below, related to Maximus’s unfavorable response, my main concern at this point is that Ms. XXXX receives appropriate medication before she has a psychotic episode. My understanding of Medicare Part D coverage policy is that, if a patient transitioning into the program has been stabilized on a given antipsychotic, antidepressant, or anticonvulsant and presents with a refill prescription, the patient’s drug plan is required to continue providing that medication; so a lack of documentation (if there were a lack of documentation) should not have been a cause for Ms. XXXX to be denied the Geodon she requires, and Ms. XXXX should have her prescription refilled as written. I have been providing XXXX with samples of Geodon since she ran out of her prescription from Medicaid, but my fear is that if this appeal is not decided in her behalf soon, I will run out of samples and she will decompensate and have to be hospitalized.

Maximus’s denial is at odds with CMS’s published formulary guidance for six classes of drugs. *See copy attached.* Antipsychotics are one of the six classes. This policy is known as the “all or substantially all” requirement. It requires that all drugs in the six classes must be included in every PDP formulary. A key part of CMS’s guidance is as follows:

“We specified that beneficiaries should be permitted to continue utilizing a drug in these categories that is providing clinically beneficial outcomes. This is because the factors described in our formulary guidance indicated that interruption of therapy in these categories could cause significant negative outcomes to beneficiaries in a short timeframe...We are also requiring special attention to patients already stabilized on these drugs before enrollment with a plan. In particular, for such patients, we generally expect that plans would not use management techniques like prior authorization or step therapy, unless a plan can demonstrate extraordinary circumstances.”

2. Statement of Disagreement.

a. I Have Proven All that is Required by Medicare Regulations to Obtain a Geodon Refill.

I respectfully disagree with Maximus’s decision to deny the Geodon as I prescribed it (160 mg twice daily) and am seeking a favorable decision from you to overturn the denial by Medco that was upheld by Maximus. Geodon at this dose level is an essential and medically necessary component of the clinical treatment of XXXX. While the dose of 320 mg per day is prescribing at a different dose than indicated by FDA recommendations, when medically necessary, this dose 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 lower doses. Failure to provide the drug as I have prescribed it is substantially likely to adversely affect the health of Ms. XXXX.

Medco’s refusal to provide the drug is inconsistent with the Medicare regulations that govern the exceptions process. CMS, in its Medicare Part D regulations related to exceptions and appeals, anticipated that physicians would request doses for drugs that exceed the recommendation set forth in package inserts and provided a process by which enrollees and their physicians could obtain an exception, and therefore, receive doses higher than indicated in the package insert.

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 the treatment of the 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 effect 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. XXXX's case is criteria *(a)*. Therefore, in accordance with these regulations, as a physician seeking an exception to a dose and/or quantity limitation, I provided oral and written supporting statements 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." In all of my telephone conversations with Medco and in my written correspondence to Medco and Maximus, I have provided an appropriate supporting statement that Geodon is medically necessary for Ms. XXXX and that the dosage, as available from Medco, was ineffective in her treatment in the past.

Ms. XXXX's clinical history and course of treatment clearly show that the dose she requires is not available, given the Medco restriction, without an exception. As is set forth above, prior to October 2002, Ms. XXXX had been treated with a variety of psychotropic agents: Mellaril, Trilaton, Prolixin, and Zyprexa. Although provided in appropriate doses over an appropriate length of time, these medicines failed to produce an appropriate treatment response. In October 2002, Geodon was added to her drug regimen, and a titration process from 40 mg to 80 mg twice daily was commenced. She had a favorable response to this and experienced fewer negative side effects. This course of treatment continued until June 2004, at which time there was an exacerbation of acute symptoms that led to an increase of the Geodon dose to 160 mg twice daily in October of that year. The regimen of 160 mg of Geodon twice a day proved effective and has continued uninterrupted since October 19, 2004, and Ms. XXXX has been stabilized with no active symptoms (i.e., paranoia, anger, or thought disruptions).

It appears to me from Maximus's statement that they "were unable to find documented evidence to support the use of the drug Geodon at the daily dose of 320 mg (160mg twice daily)," Maximus believes that I need to show medical and scientific evidence to justify the actual dose rather than showing the actual course of treatment. They seem to be misinterpreting the regulations. There are two ways to prove medical necessity in a case where there is a dose limitation (i.e., the criteria specified above by *(a)* **or** *(b)* at 42 CFR §423.578 (b)(5)(iii)) and there is a major difference between the two. Under criteria *(a)*, a physician must provide a statement of fact embedded in the patient's clinical history which shows that the dose restriction has been ineffective. Under criteria *(b)*, a physician must provide a statement of judgment or probability as to the future course of a person's treatment, if, for example, a higher dosage is proposed. In this case, medical necessity is not a matter of my judgment based on the factors delineated in criteria *(b)*, but it is a matter of the medical facts and the inadequate treatment response that Ms. XXXX has had in the past.

I also take exception to Maximus' statement explaining their denial that in order for a drug to be covered as a Part D drug, a drug must meet the following criteria: (i) It is approved by the FDA; (ii) It is used and sold in the US; (iii) It is used for a medically accepted indication; and (iv) It includes uses supported by one or more citations included or approved for inclusion in the American Hospital Formulary Service Drug Information, US Pharmacopoeia-Drug Information, and DRUGDEX Information System. Geodon meets all of these criteria, and it is, in fact, a covered drug. This case is not a matter of off-label drug use for a non-FDA approved indication. The criteria provided are not relevant to a denial that is inappropriate since the drug in question is, in fact, covered under Part D and Ms. XXXX's treatment history clearly establishes her need for the drug at the prescribed dose.

b. Medical Practice Supports the Refill of Ms. XXXX's Geodon Prescription.

As is set forth above, CMS understood that there would be a need for exceptions to dose limitations and by regulation provided for a method that would allow an enrollee to obtain a covered drug at a dose prescribed at a different dose than indicated. In addition, although the dose of 160 mg twice daily is higher than the FDA recommended dosage, prescribing at higher doses than recommended is a widespread and a well accepted part of medical practice. In fact, professionally recognized treatment guidelines specifically address the issue of higher dosing when there is an inadequate treatment response; i.e., it is medically necessary. See, for example, *The Expert Consensus Guideline Series, "Optimizing Pharmacologic Treatment of Psychotic Disorders"*, *The Journal of Clinical Psychiatry*, Vol. 64, Supplement 12 (2003). See also the *American Psychiatric Association's "Practice Guideline for the Treatment of Patients with Schizophrenia, 2nd Edition"*, *The American Journal of Psychiatry*, Vol. 161, No. 2, February 2, 2004. Therefore, based on Ms. XXXX'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 as contemplated by 42 CFR §423.578 (b)(5)(iii) should be granted.

c. Ms. XXXX Meets the Amount in Controversy Requirement.

The value of Ms. XXXX's claim is in excess of \$110. I estimate that her Geodon would cost her \$1,121.70 per month if paid out of pocket or \$13,461.48 for 2006.

3. Conclusion.

Medco's denial of Ms. XXXX's medication should be overturned. As stated, XXXX is a Medicare beneficiary entitled to benefits under the Part D prescription drug program. She suffers from a medically diagnosed mental illness condition and has been actively treated since October of 2004 with 160 mg Geodon twice daily.

As required by regulations, I have provided documentation that the doses available under Medco's dose restriction have been ineffective in treating her disease. Moreover, Medco's basis for denial appears to be noncompliant with CMS program regulations and policy and is a failure "substantially to provide to a Part D Plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D Plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee". See 42 CFR §423.752(a)(1). Therefore, I respectfully request that the prescription denial be overturned and that she receive the medically necessary medications that she has been using to treat her condition since October of 2004.

If you have any questions or need any further information, please let me know.

Sincerely,

XXXXX, M.D.