

VIA ELECTRONIC AND OVERNIGHT MAIL

September 21, 2006

Judge Wanda Kamphuis Zapota
OMHA Mid-West Field Office
BP Tower, Suite 1300
200 Public Square
Cleveland, Ohio 44114-2316

RE: Request for Appeal for XXXX XXXX
ALJ Appeal No. XXXXXXXXX
HIC No. XXXXXXXXX

Dear Judge Zapota:

I am writing to provide you with background about XXXX XXXX's appeal and, in particular, her diagnoses, her medical and prescription history, her need for treatment with Provigil, and the basis for objection to the decisions of SilverScript and Maximus about its medical necessity in Ms. XXXX's case.

Ms. XXXX, who has been on Provigil since 2001, has diagnoses of obstructive sleep apnea (OSA) and major depressive disorder. These comorbidities have resulted in symptoms of fatigue and excessive sleepiness. There is a body of scientific evidence to support the use of Provigil for treatment of these symptoms. SilverScript, her Prescription Drug Plan under Medicare Part D, denied payment for her prescription of Provigil, as did Maximus, the Part D IRE/QIC.

Provigil is "reasonable and necessary" as defined by the Social Security Act for the treatment of Ms. XXXX's OSA and/or the symptoms of fatigue and excessive sleepiness associated with her diagnosis of depression. Furthermore, Provigil is a covered drug under Part D and is being used for a medically accepted indication as required.

1. Introduction and Background.

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

Ms. XXXX is a 47-year-old dual eligible Medicare beneficiary suffering from a number of medical and psychiatric problems, including the following: recurrent major depressive disorder, schizoaffective disorder, chronic pain, gastroesophageal reflux disease (GERD), hypertension, hypothyroidism, dyslipidemia, bronchial asthma,

chronic obstructive pulmonary disease, osteoporosis, trigeminal neuralgia, degenerative arthritis of the lumbosacral spine, urinary incontinence, cognitive impairment, sleep apnea, and small strokes. She also has a past history of polysubstance abuse and hospitalizations to treat her psychiatric condition and adjust her medications.

As you can see from the number of medical and psychiatric conditions listed, Ms. XXXX is a medically complex and vulnerable beneficiary who requires me to make difficult and highly individualized decisions regarding her treatment. I have been working with Ms. XXXX since May 10, 2001, and with appropriate medication her condition has been stabilized and improved and she has been able to maintain her activities of daily living (ADLs) and live by herself. A key medical component of her treatment plan has been the use of Provigil at 200mg per day.

When I first saw Ms. XXXX, she walked with a cane, was apathetic, was slumped over with no energy, depressed, and very tired. Ms. XXXX reported that she had been diagnosed with obstructive sleep apnea (OSA) and had been prescribed the drug Provigil. In an attempt to treat Ms. XXXX's depression, schizoaffective disorder, and excessive sleepiness, I considered changing her medications, but given her medical and psychiatric history, I had very few choices available to me. To treat fatigue and excessive sleepiness many psychiatrists would start with certain controlled substances, but I could not prescribe a controlled substance, such as Ritalin, due to Ms. XXXX's past history of polysubstance abuse. In fact, to prescribe such a controlled substance would be dangerous for the patient, medically unethical, and would violate the requirements of my medical license.

A medically available alternative to treat the root cause of Ms. XXXX's fatigue and excessive sleepiness was Wellbutrin. I prescribed Wellbutrin and Ms. XXXX took the Wellbutrin, as I instructed, but Ms. XXXX had to discontinue its use, because Wellbutrin was causing her to become psychotic. Since I could not prescribe a controlled substance and since Wellbutrin had terrible side effects for Ms. XXXX, I decided to treat Ms. XXXX with the previously prescribed Provigil, alter her other medications, and provide her with psychotherapy. Since there were no other alternatives, Provigil was, and still is, the only medically appropriate option for Ms. XXXX.

When I first started to treat Ms. XXXX, she reported that she could not tolerate the CPAP device often used to treat sleep apnea because she was claustrophobic and was unable to tolerate the CPAP mask. In addition, Ms. XXXX sleeps in an upright position and the CPAP is not effective when the patient sleeps in an upright position. Since it is not necessary for a patient to use a CPAP when taking Provigil, I did not require Ms. XXXX to use one. While Provigil may be used as an adjunct to a CPAP machine, there are no FDA proscriptions that state it must be used as an adjunct to a CPAP machine.

I have since confirmed that Ms. XXXX has OSA and that a CPAP would not be a good alternative for her. On January 23, 2006, Dr. Marvin Wooten, M.D., at Columbia Hospital – Milwaukee Regional Sleep Disorder Center, performed a nocturnal polysomnogram. This study confirmed that Ms. XXXX has OSA and that a CPAP is not required due to the high probability of poor tolerance and poor compliance.

Provigil has not only proven effective in treating the symptoms of Ms. XXXX's OSA, but has also enabled me to successfully treat the fatigue and excessive sleepiness associated with her depression. (In truth, it is often difficult to differentiate between the two.) Incomplete remission is a common complication of treatment with medications for depression. Despite adequate pharmacotherapy, depressed patients often experience fatigue and sleepiness as residual symptoms or as side effects of drug treatment. Fatigue and sleepiness symptoms in patients with incomplete remission during antidepressant therapy have been shown to abate with the administration of Provigil. Medical literature supports these findings. (See the article attached entitled *Modafinil Augmentation of SSRI Therapy in Patients with Major Depressive Disorder and Excessive Sleepiness and Fatigue: a 12-Week, Open Label, Extension Study*. Exhibit 1) Because of this it is common practice among psychiatrists to prescribe Provigil to patients with depression with or without OSA, in order to improve the patients' psychiatric condition.

On a couple of occasions, Ms. XXXX was without Provigil for a week or more. During those periods, she was unable to function and needed increased intervention from her family. She slept late, had slurred speech, stayed at home all day, and her depressive symptomatology became more acute. When Provigil was reintroduced, Ms. XXXX was able to function again – her depression was better (i.e., her clinical symptomatology was reduced) and she was and is able to maintain her ADLs.

The medical necessity for the Provigil has been affirmed previously by independent medical opinion. In 2003, Ms. XXXX's prescription drug coverage changed to Blue Cross and Blue Shield (BCBS). BCBS denied Ms. XXXX's prescription of Provigil. On appeal, I worked with BCBS's physician reviewer, who overturned the initial negative coverage decision, making a decision based on the facts of Ms. XXXX's case that Provigil was, in fact, a medically necessary component of her treatment. BCBS provided coverage for Provigil as a medically necessary component of Ms. XXXX's care until her insurance coverage changed.

Since 2001, with medication and on-going supportive therapy, I have been able to provide medically appropriate treatment for Ms. XXXX (maintaining clinical stability and/or achieving improvement, especially as measured by her ability to maintain her ADLs). Based on my decades of clinical experience, I can only attribute Ms. XXXX's therapeutic response in large part to the 200mg of Provigil that she is currently taking each day. Ms. XXXX's therapeutic achievements face a high probability of regression if

she is forced to stop taking Provigil, as she has no alternatives. Without Provigil, she would be unable to take care of herself, would be at risk of falling and fracturing her bones (since Ms. XXXX has a history of osteoporosis), cognitive impairment, and a worsening of her underlying medical and psychiatric conditions.

In conclusion, it is my clinical opinion that Ms. XXXX would be unable to function without Provigil and could well require hospitalizations or nursing home placement. I have received calls from Ms. XXXX's husband expressing the family's concern that Ms. XXXX may not continue to receive her Provigil and as a result, her condition will deteriorate to a point where she may become a danger to herself without nursing home care.

b. Ms. XXXX's Prescription of Provigil Was Denied by SilverScript and Maximus.

In May 2006, I requested prior authorization from SilverScript for 200mg of Provigil for Ms. XXXX to be taken once a day in the morning. I explained in my documentation that the Provigil was medically necessary for Ms. XXXX to get out of bed.

SilverScript denied coverage of Provigil, stating that Ms. XXXX did not have a diagnosis of narcolepsy, obstructive sleep apnea, or Shift Work Sleep Disorder.

Since Ms. XXXX, who has been on Provigil since 2001, does have a diagnosis of obstructive sleep apnea, I requested a redetermination from SilverScript, which was also a denial. I, therefore, requested a reconsideration from Maximus. On June 23, 2006, Maximus provided an unfavorable decision, stating, in part, the following:

Provigil has been demonstrated to be effective for excessive daytime sleepiness as an adjunct to therapy with a CPAP machine. The enrollee does not use the CPAP device. The medication has not been shown to be efficacious when used without a CPAP machine. The enrollee does not meet the formulary criteria for the medication and the current evidence available does not indicate Provigil is the only agent effective for the enrollee.

c. Obstructive Sleep Apnea, Fatigue, Excessive Sleepiness, and Provigil.

Obstructive sleep apnea is a sleep disorder in which a person repeatedly stops breathing, or experiences shallow breathing for short periods of time during sleep. These episodes can disrupt the quantity and quality of a person's sleep, resulting in

excessive sleepiness during waking hours. Obstructive sleep apnea is commonly referred to as OSA.

The most common treatment for OSA is the use of nasal CPAP, or nasal continuous positive airway pressure. Nasal CPAP is delivered by a mask-like device and pump that work together to keep the airway open with air pressure. Even though it is the most common treatment for OSA, it is not the only way to treat OSA. Many people who use a CPAP continue to have excessive sleepiness and use Provigil, a medication that treats excessive sleepiness caused by certain sleep disorders, in addition to nasal CPAP. Other people do not use the CPAP, but still use Provigil to counteract excessive sleepiness as a result of OSA. A CPAP is very confining and many people feel it is claustrophobic and intolerable. This is especially common for individuals who have psychiatric conditions.

In addition to its effectiveness for treating OSA, there is drug compendia support that Provigil works to improve the symptoms of depression, decrease fatigue, and improve wakefulness in patients with excessive daytime sleepiness. (The three drug compendia that support medically accepted indications under Part D are American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, and the DRUGDEX Information System.) For example, the compendia indicate that the evidence favors the efficacy of Provigil for the treatment of fatigue. The compendia also indicate the efficacy of Provigil in improving wakefulness for patients with excessive daytime sleepiness. (These symptoms are referenced in the compendia in association with narcolepsy.) It should be noted that although Ms. XXXX does not have a diagnosis of narcolepsy, she has all the symptoms of that disorder, and the compendia support the use of Provigil for the treatment of those symptoms (Exhibit 2).

Therefore, the basis for SilverScript's and Maximus's denials is not supported by the medical facts of Ms. XXXX's case or the evidence for efficacy of Provigil for the treatment of her condition.

2. Statement of Disagreement.

a. Provigil is Medically Necessary for the Treatment of Ms. XXXX's Condition.

I respectfully disagree with SilverScript's and Maximus's decisions to deny the Provigil as I prescribed it (200mg daily) and am seeking a favorable decision from you to overturn their denials. As I understand it, with the exception of certain statutorily excluded medications, Medicare Part D covers all drugs that are reasonable and necessary for the treatment of an illness and are used for a medically accepted indication. Plans must provide beneficiaries with access to medically necessary drugs that are necessary for treatment of the beneficiary's medical conditions.

I strongly disagree with SilverScript's assertion that Ms. XXXX does not have OSA. Ms. XXXX was diagnosed with OSA on at least two (2) occasions. Provigil is medically necessary to treat Ms. XXXX's OSA regardless of her inability to use a CPAP machine.

Notwithstanding her OSA, Provigil is also medically necessary to treat the fatigue and/or excessive sleepiness associated with Ms. XXXX's depression and the medication regimen used to treat it. Overall, Ms. XXXX's clinical condition has been maintained or improved as a direct result of Provigil to treat the above noted symptoms.

I also strongly disagree with Maximus's conclusion regarding medical necessity. It has been noted in other Maximus decisions that:

Maximus has been directed by the Centers for Medicare and Medicaid Services to rely on clinical information in the enrollee's medical record, data supported by the drug compendia, and peer reviewed evidence based medical literature. (See Exhibit 3)

In this case Maximus failed to duly consider the factors it is required to rely upon. The real issue here is whether the 200mg dosage of Provigil is medically necessary for Ms. XXXX. Determining medical necessity involves many variables, albeit the final evidence of medical need on an individual basis is straightforward. Ms. XXXX is a complex individual with many issues and it is very important to look at the facts of her particular situation. The key fact in support of medical necessity is that Ms. XXXX has been medically stable over a course of care and treatment for more than five (5) years using Provigil. Moreover, as noted above, there is evidence in the recognized compendia to support efficacy of Provigil for the treatment of her fatigue and excessive sleepiness.

Given the fact that Ms. XXXX cannot take controlled substances, Provigil is the only medically appropriate alternative to treat her fatigue and excessive sleepiness. I have not required Ms. XXXX to use a CPAP machine, since she cannot tolerate it because of her claustrophobia and the fact that she sleeps in an upright position would make it ineffective. Furthermore, there is nothing in standard practice or the literature that states that a CPAP is necessary for the prescription and use of Provigil. The prescription of Provigil without a CPAP is consistent with the practice of psychiatrists who treat patients with depression who are experiencing incomplete remission due to symptoms of fatigue and excessive sleepiness. Failure to provide the drug as I have prescribed it will adversely affect the health of Ms. XXXX.

Ms. XXXX is now living on her own and maintaining her ADLs. Without Provigil, Ms. XXXX may face hospitalization and might have to be placed in a nursing home since she would not be able to function without the kind of assistance offered by such a facility. This is especially evident given my experience with Ms. XXXX in the past when she was

unable to obtain and take Provigil. Her condition worsened to the point where she could no longer function without intervention. It is, therefore, reasonable and necessary to provide her with the Provigil as prescribed. Furthermore, Provigil is a covered Part D Drug because it is being used for a medically accepted indication and its use is supported, as required, by the drug compendia.

Maximus, in its decision, may have been working without a complete medical history of Ms. XXXX, and under the incorrect assumption, in my view, that a CPAP is necessary for a patient who takes Provigil. Ms. XXXX cannot take any controlled substances. To my knowledge, there is no medical or ethical alternative to counteract Ms. XXXX's excessive sleepiness other than Provigil. I have decades of psychiatric experience and have seen firsthand the clinical benefits of Provigil for fatigue and excessive sleepiness created by OSA and depression.

b. Ms. XXXX Deserves all Medically Necessary Drugs to Treat Her Medical Condition(s).

Aside from the issues I set forth above related to Maximus's unfavorable decision, my overriding concern at this point is that Ms. XXXX receives appropriate medication before she loses her ability to function and requires hospitalization or nursing home care. Ms. XXXX has been successfully using Provigil to treat her OSA, fatigue, and excessive sleepiness for over five (5) years. To ensure Ms. XXXX's continuity of care, Ms. XXXX should have her prescription refilled as written.

3. Conclusion: The Coverage Denials Should be Reversed.

SilverScript's and Maximus's denials of Ms. XXXX's medication should be overturned. In this instance Provigil is a covered Part D drug being used for a medically accepted indication and is reasonable and necessary for the treatment of Ms. XXXX's medical condition.

As stated, XXXX XXXX is a Medicare beneficiary entitled to benefits under the Part D prescription drug program. She suffers from OSA and major depressive disorder and has symptoms of fatigue and excessive sleepiness. She has seen a significant therapeutic response since being treated with 200mg of Provigil daily. Provigil is a Part D Drug, being prescribed for a medically accepted indication. I, therefore, respectfully request that the prescription denial be overturned and that she receive the medically necessary medication that she has been using to treat her conditions .

Attached for your reference is a copy of my CV (Exhibit 4). It is my understanding from discussions with your office that you will determine whether this letter is to be faxed to Maximus and SilverScript. If you would like me to fax the letter to them, please contact YYYYY, J.D., who is working with me on this case, at 555-555-5555. If

you have any questions or need any further information, please do not hesitate to contact me or Mr. YYYYY.

I look forward to discussing the case and our position in more detail during our hearing on Monday, September 25, 2006.

Sincerely,