

Dina B. Berlyn, Esq.
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Hamden, CT 06517
Dina.berlyn@cga.ct.gov
w-860-240-8629 c-203-530-2529

FTR

March 15, 2012

Good afternoon Senator Crisco, Representative Megna and members of the Insurance and Real Estate Committee. I am here to testify in support of SB 410, AN ACT CONCERNING ADVERSE DETERMINATION REVIEWS.

Most unfortunately, I have experienced first hand the appeals process for healthcare coverage denials. This experience is why I believe that SB 410, is needed. At the beginning of the process in my case it was unclear that the denial was coming from the pharmacy benefits manager; Caremark would not give straight answers. One might think that the insurer, pharmacy benefits manager, or utilization review organization should at least tell the patient when they deny a claim but apparently this is not true.

Once it became clear that my doctor had renewed the prescription appropriately (a fact that I had to track down) and the problem was a denial by Caremark, I began the appeal process. I lost at the first two rounds of internal

appeal; there is not much of an opportunity to present your case in these rounds especially since the insurer does not disclose their records in your case to you. I made repeated requests to Caremark for their records in my case (as well as for any information) but NEVER received them. I did receive a fax which started at page 52 and purported to be the record but in fact it was a copy of the appeal form from the Department of Insurance (which I already had). What were they hiding in the prior 51 pages? Apparently I will never know.

Once the internal rounds of appeal were done, I filed an external appeal with the state Department of Insurance. I spent over 20 hours researching and writing this document. I included journal articles supporting the use of Provigil for fatigue in MS (it is the most common symptom in the disease). I pointed out that this drug has been extraordinarily effective in my case and I noted that Caremark made a number of claims that were not backed up by any evidence I could find (nor would they provide evidence to me). Unfortunately, there was no requirement that Caremark provide me with the supposed evidence that they were using to make these claims. I had to make the best case I could for the use of this drug for my condition without any knowledge of what Caremark's case against me was.

Once the Department of Insurance receives an external appeal, it sends the appeal out to the external reviewer and to the insurer. When Caremark received my letter they chose to cover the prescription rather than go through the

appeal. I believe that they feared that if they lost this appeal, they would not be able to deny others with a prescription for the same drug for this condition. When a healthcare provider prescribes a drug for a specific condition which has been effective for a patient and for which there is evidence of effectiveness, an insurer should not be allowed to substitute its judgment for that of the skilled providers. In a perfect world, the insurers would carry the burden of proof. They have the information and in general at law, the burden of proof is placed on the party with the information. However, since it seems unlikely that the burden of proof will be shifted, the patient MUST be granted access to all the information related to the case.

In addition, a patient should not be forced to forego a needed prescription during the course of the appeal; this can create an undue hardship on these patients. This bill contains reforms which would assist patients in receiving the care they require and prevent insurers from substituting their judgment for that of the skilled medical professional.

While PA 11-58 did make significant reforms to the appeals process such that the process in Connecticut meets the minimum requirements under the federal Patient Protection and Affordable Care Act we can and should do more. These federal requirements are meant to be a floor; the states are free (perhaps encouraged) to offer additional protections to patients. The State of Connecticut should offer its citizens the additional protections provided by this bill.

I am most appreciative of your efforts on these issues of extraordinary importance to Connecticut's citizens.

I am including a copy of my appeal letter as well as of the letters that I received from Caremark. If you are interested in viewing the journal articles that I cite in my appeal, I would be happy to share those with you. What is also extraordinarily disturbing in the letters from Caremark is that some of the letters claim erroneously that the prescriptions was for "cognitive dysfunction." The prescription was for fatigue related to multiple sclerosis (the most common symptom of this disease). I do not have nor have I ever had cognitive dysfunction; I have reviewed all of the medical records from my doctor and cognitive dysfunction is NEVER mentioned. I find this unacceptable and disturbing. Caremark denied coverage based on inaccurate information that they created.

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Connecticut Insurance Department
P.O. Box 816
Hartford, CT 06142-0816
Attn: External Appeals

May 28, 2009

Dear Gentlepersons:

This letter is my appeal of the denial of coverage for Provigil which I was prescribed for multiple sclerosis related fatigue.

Facts of my case

1. I am a patient with multiple sclerosis. I was diagnosed in 1997.
2. I have suffered from fatigue. Fatigue is the most common (and perhaps most debilitating) symptom of MS.
3. I had tried Amantidine but it did not work all that well and it appeared to contribute to a concerning increase in my liver enzymes in 2003 (ALT and AST about 3x normal).
4. I was prescribed Provigil (modafinil) beginning in 2004. It worked extremely well. It is medically necessary. Clearly there is sufficient evidence as to the effectiveness of Provigil. There is "credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community" and it is "consistent in policy issues involving clinical judgment" as Sec. 38a-513c requires.
5. There is substantial evidence that provigil is effective. I have attached copies of journal articles, the letter to Caremark from my doctor, my letters to Caremark, and Caremark's letters to me.
6. I have been on provigil for approximately 5 years and then suddenly for some reason Caremark decided to deny prior authorization. **I HAVE REQUESTED THAT CAREMARK SEND ME THE COMPLETE RECORD OF MY CASE. I MADE THIS REQUEST ON APRIL 16 AND HAVE NOT YET SEEN THE RECORD.** It

is difficult to fight this denial of coverage when Caremark refuses to provide me with information as to why the coverage was denied.

In response to my April request for the full record, I got a phone call on May 26, 2009 asking me if I had received a package they claimed to have sent on May 18. I had not received this package. They then said they would overnight another copy. What appeared the next day was a letter (attached) with an additional copy of the Insurance Department's external appeal form. Although the letter said the record of my case would be enclosed it was not. The letter was dated May 18 but the fax was dated April 17. I have enclosed these items. The fax indicates that the form is pages 52-60. Pages 1-51 appear to be missing.

7. I lost on both rounds of the internal appeals process at Caremark DESPITE convincing evidence as to the effectiveness and medical necessity of provigil in my case provided by both my healthcare provider, Dr. Jana Preiningerova (who specializes in treating MS patients) and me.

8. Caremark has made inaccurate assertions in regard to the evidence of the efficacy of Provigil:

In its letter of April 14, 2009 Caremark asserts that "the only peer reviewed study in the literature finds provigil to be of no value for MS fatigue." This is untrue. I have included three journal articles that do in fact find that Provigil is significantly helpful for MS patients with fatigue:

a. *Modafinil effects in multiple sclerosis patients with fatigue.* J Neurol. 2009 Apr;256(4):645-50. Epub 2009 Apr 9. Lange R, Volkmer M, Heesen C, Liepert J showed that Modafinil (as compared with placebo) improved fatigue, focused attention and dexterity and enhanced motor cortex excitability.

b *Efficacy and safety of modafinil (Provigil) for the treatment of fatigue in multiple sclerosis: a two centre phase 2 study* by Rammohan, Rosenberg, Lynn, Blumenfeld, Pollak and Nagaraja in J. Neurol Neurosurg Psychiatry, 2002 Feb; 72(2): 179-83 demonstrated that a 200 mg per day dose of modafinil significantly improves fatigue in MS patients while a 400 mg per day dose does not.

c. In addition, *Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study* by Zifko, Rupp, Schwarz, Zipko, and Maida in J. Neurology also found that a 200 mg per day dose of modafinil significantly improves fatigue and sleepiness and is well tolerated by patients with MS.

Caremark makes a claim that in the only peer reviewed journal article no effect was shown on fatigue in MS. As you can see above there are at least three peer reviewed journal articles that show significant effect.

I have also included citations to articles showing the effectiveness of Provigil on other MS symptoms.

9. Despite my repeated requests, Caremark has chosen not to disclose the citation of the journal article that it claims showed no effect. However, I assume it is Stankoff, et. al. (2005). A closer examination of this article shows that the study used a **non-standard dose and a non-standard dosing schedule** (see attached response to Stankoff). Usually, MS patients are given Provigil in a single dose first thing in the morning. In the Stankoff study patients were given one dose in the morning and one dose at mid-day. Since Provigil has a 15 hour mode of action, it is quite possible (even probable) that a mid-day dose could interfere with a patient's sleep thus destroying any positive effect that the drug had on fatigue. In addition, the Rammohan study showed that 200mg was more effective than 400mg for MS patient' with fatigue but the Stankoff study dosed at 400 mg.

Provigil allows me to remain employed. Prior to my taking this drug it was very difficult for me to function in the afternoon at work. It is clear that Provigil is effective in my case. Provigil is medically necessary for me if I am to continue to function at my current level.

- a. My job as Counsel and Executive Aide to the Majority Leader of the State Senate requires that I be alert with a crisp mind at all times. Provigil allows me to do my job and thus is medically necessary.
- b. Although my job is not technically "shift work" it does have certain similar properties. There are days in which I am required to work very late into the night and then be back at work the next morning. This would not be possible without the assistance of Provigil.

I ask that you overturn Caremark's decision to deny me access to a medically necessary drug which allows me to live my life and contribute to society. Clearly there is sufficient evidence as to the effectiveness of Provigil. **There is "credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community" and it is "consistent in policy issues involving clinical judgment" as Sec. 38a-513c requires.**

The fact that there are differing reports in academic literature makes it all the more important that this decision be left to the judgment of the treating physician. Please note that the one article that found that Provigil was not effective in MS had flawed methodology and a small sample size. MS is a very individual disease; no two of us

have exactly the same disease. Physicians who specialize in treating MS patients are the ones who are best able to make decisions as to which drugs are medically necessary for their patients. Please help me continue to be a productive member of society.

Thank you,

Dina B. Berlyn, Esq.

Attachments:

Letter to CVS from Dr. Preiningerova
Letter from Senator Looney
Letter from Dina Berlyn to CVS
CVS letters to Dina Berlyn dated 3/16, 3/19, 4/3, 4/9, 4/14
Email correspondence with CVS
CVS letter dated May 18 with fax of Ins. Dept. forms
Journal Articles: Lange et.al.; Rammohan, et al; Zifko, et al; response to Stankoff.
CGS 38a-513c

Provigil effectiveness on other MS symptoms

Modafinil improves primary nocturnal enuresis in multiple sclerosis.

Carrieri PB, de Leva MF, Carrieri M, Buongiorno M.
Eur J Neurol. 2007 Mar;14(3):e1. No abstract available.

ECTRIMS: Thursday, September 28, 2006, 15:30 - 17:00

Final analysis of combination therapy (Provigil® + Avonex®) in the treatment of cognitive problems in patients with relapsing-remitting multiple sclerosis

J.A. Wilken, M.T. Wallin, C.L. Sullivan, R.L. Kane, H. Rossman, S. Lawson, J. Simsarian, C. Saunders, R. Shin, J. Mikszewski, D. Kerr, M.E. Quig (Washington, Baltimore, Farmington Hills, Fairfax, Arlington, USA)



STATE OF CONNECTICUT
INSURANCE DEPARTMENT

Consumer Services Division
Phone: 860.297.3900, Ext. 3945
Fax: 860.297.3872
cid.ec@ct.gov

June 1, 2009

Dina B. Berlyn
30 Morris Street
Hamden, CT 06517

Re: *Request for External Appeal Review*
Department File: ER2009-110
Applicant: Dina B. Berlyn

Dear Ms. Berlyn:

During the process of setting up your external appeal, CVS Caremark notified our Department that your prescription for Provigil will be covered.

Your external appeal will be withdrawn and your \$25 fee returned under separate cover.

Sincerely,

A handwritten signature in cursive script that reads "Wendy Manemeit".

Wendy P Manemeit
Associate Examiner

Enclosure(s)

www.ct.gov/cid
P.O. Box 816 Hartford, CT 06142-0816
An Equal Opportunity Employer



2211 Sanders Road | Northbrook, Illinois 60062

May 18, 2009

Ms. Dina Berlyn
30 Morris St.
Hamden CT 06517

*was not included.
all I got was this tax
starts @ P52*

Dear Ms. Berlyn;

CVS Caremark administers the prescription portion of the State of Connecticut health plan. In response to your request attached, please find copies of our file regarding your request for coverage for Provigil®.

Included in the attachment is the review of coverage performed by third party independent vendor; Medical Review Institute of America. The independent reviewer is a physician who is board certified by the American Board of Psychiatry and Neurology on Neurology and member of the American Academy of Neurology.

Your letter indicates your disagreement with this coverage decision. Therefore we recommend that in compliance with the terms of your benefit plan, an appeal is filed with the Connecticut Department of Insurance, if you haven't done so already.

We are sorry for the inconvenience that you have experienced when discussing your prescription coverage with our Customer Service Representatives. Our goal is to provide you with the level of service that exceeds your expectations and in this case, we clearly did not do that.

Should you have any additional questions regarding your Provigil prescription coverage, please contact our Service Recovery Team at: 1-800-749-6199 ext. 6822.

Sincerely,

Lynne Anderson
Director, Operations Excellence
Service Recovery Unit

CC: MRIOA File- April 8, 2009

Connecticut Insurance Department

External Appeal Consumer Guide

Connecticut General Statute 38a-478n gives you the right, under specific circumstances, to an external appeal for coverage of medical services or supplies denied to you by your health plan. Coverages may have been denied through a process known as utilization review or after retrospective review of a claim submission.

To understand how the external appeal process works, you should first have an understanding of what is meant by "utilization review" and "retrospective claims denial".

UTILIZATION REVIEW

Utilization review (UR) is the prospective or concurrent assessment and decision-making process used to determine the medical necessity of a medical treatment or service. This does not include a denial of a claim for which prior approval was not required. Utilization review may be performed by your health plan or an independent utilization review company on behalf of your health plan.

Each health plan determines which services are subject to utilization review. Examples of medical treatments or services commonly subject to UR include, but are not limited to:

- Hospitalization, including length of hospital stay;
- Surgery;
- Mental health & substance abuse;
- Specialist referrals;
- Outpatient services, such as physical therapy.

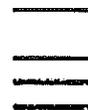
Depending on your contract, you or your provider will contact your health plan or the UR company acting on behalf of your health plan, to request authorization for a specific service or treatment. Based on information submitted by your provider, the UR contact will assess the medical necessity of the proposed treatment and either authorizes or denies coverage for the requested treatment.

RETROSPECTIVE CLAIMS DENIAL

Retrospective claims denial is when a service that was not subject to prior approval is denied as not "medically necessary" when the claim is submitted.

INTERNAL APPEAL FOR A DENIED MEDICAL TREATMENT OR SERVICE

Every health plan has appeal procedures. When you are denied coverage for a medical treatment or service, you may appeal the decision to your health plan or UR company acting on behalf of your health plan. This appeal is known as the "internal appeal." Many plans have more than one level of internal appeal. Consult your employer or coverage documents to find out how to make an appeal.



ELIGIBILITY FOR EXTERNAL APPEAL

To be eligible for the external appeal process through the State of Connecticut Insurance Department, you must satisfy the following requirements:

- You must have exhausted the internal appeal procedures of your health plan.

Your health plan or utilization review company acting on behalf of your health plan is required to provide you with written notification that you have exhausted the internal appeal process.

- Your completed "Request for External Appeal" form must be received by the Insurance Department within 60 days of receiving the written notification that the internal appeals have been exhausted.

For purposes of this process, the number of days is based on calendar not business days. The 60 day time frame will commence 7 days after the date on the final denial letter, unless other evidence of a later receipt date is provided. Once this 60 day period expires, you will not be eligible for the external appeal process.

***Please note:** You may have a pending complaint filed with the Consumer Affairs Division of the Insurance Department concerning your health care benefits. This does not constitute a request for an external appeal. You must file for a separate external appeal on the request form and follow the guidelines provided in this brochure.

- You must be actively enrolled in a health care plan at the time the service was requested as well as when the service is provided.
- External appeal is only for a service or procedure that is covered in your contract.

You may only use this external appeal process to appeal for services that are covered in your contract. The appeal process cannot be used to expand the coverage of your contract. For example, this process cannot be used to authorize coverages that are exclusions in your contract. Be sure to review the listed exclusions in your contract.

- The denial of medical treatment or services must be based on "medical necessity."
- Your appeal cannot be for workers' compensation claims.
- Your health plan cannot be a non-governmental "self-insured" plan.

Your employer can tell you if your plan is "self-insured." The Insurance Department has no jurisdiction over "self insured" plans. The Insurance Department's Consumer Affairs Division (1-800-203-3447) can direct you to the appropriate agency for assistance.

- Your health plan cannot be offered as part of a Medicaid, Medicare or a Medicare Risk program.

FILING THE EXTERNAL APPEAL

You, or your provider with your written consent, may request an external appeal. The "Request for External Appeal" and all supporting documents for the external appeal must be received by the Insurance Department within 60 calendar days of receiving the final denial letter. The following items must be included in your

1. The *non-refundable* filing fee of \$25 (Please make check or money order payable to: *Treasurer-State of Connecticut*).

Note: The fee will be waived by the Insurance Commissioner for indigent individuals or those unable to pay. Indigent individual means an individual whose adjusted gross income (AGI) for the individual and spouse, as certified on the request form, from the most recent federal tax return filed, is less than two hundred percent of the federal tax poverty level. Table 1 (below) lists the 2007 poverty levels. If your AGI is below the figure corresponding the number of members in your family*, then the \$25 fee will be waived.

Table 1

Number of Family Members	200% of 2007 Federal Poverty Level
1	\$20,410
2	\$27,380
3	\$34,340
4	\$41,300
5	\$48,260
6	\$55,220
7	\$62,180
8	\$69,140

*Add \$6,960 for each additional family member.

- Evidence of being an enrollee of the plan (photocopy of your insurance card).
- A copy of the letter from your health plan or UR company acting on behalf of your health plan indicating that all internal appeal mechanisms have been exhausted.
- A completed "Request for External Appeal" form that includes a medical release signed by the patient (on page 2 of the "Request" form.) You may contact the Insurance Department for copies of the form or download it from the Department's website.
- Proof that the service in question is a covered benefit. This is typically a copy of your entire policy handbook or certificate of coverage that details all benefits and provisions. A summary of benefits is not acceptable. If you do not have a copy of your policy, your health plan can provide one to you with your written request. When you e-mail or write to your health plan for a copy of your policy booklet or certificate of coverage, they are required to provide it to you within five (5) business days of receiving your request. If you belong to a self-insured governmental plan, contact your employer. In lieu of the actual handbook or certificate of coverage, the health plan may send a letter certifying that the service is a covered benefit or send detailed instructions on how to access the handbook or certificate of coverage electronically.

Note: If you are close to the 60 day deadline for submitting your external appeal application and have requested a copy of your handbook or certificate of coverage from your health plan but have not yet received it, **DO NOT DELAY** in sending the "Request for External Appeal" form and all other attachments to the Insurance Department. In lieu of the proof the service is covered, attach a copy of your dated written letter or e-mail to the health plan requesting the handbook or certificate of coverage. This must be submitted with your "Request" form so that your request will not be rejected by the External Appeal entity as incomplete. If the health plan fails to provide the required proof within 5 days,



the external appeal entity will make the presumption that the service is covered. As stated earlier, this presumption of coverage is for purposes of continuing the external appeal process and does not guarantee payment of the service.

THE APPEAL PROCESS

The Insurance Department contracts with independent entities to review the appeal. Once a complete application is received, the Insurance Commissioner will assign the appeal to an external entity for review. This entity will conduct a preliminary review to determine the eligibility of the appeal. If your appeal does not meet the conditions described in the "Eligibility for External Appeal" portion of this brochure, your appeal will be ruled ineligible. The external appeal entity will contact you and the Insurance Commissioner within 5 business days of its receipt, as to whether the appeal has been accepted or denied for full review. If the appeal is rejected in the preliminary phase, the external appeal process ends.

If the appeal is accepted, the reviewing entity will complete the full review and forward its decision to the Insurance Commissioner within 30 business days of completing the preliminary review. The Insurance Commissioner shall accept the decision of the external appeal entity and notify you or your doctor and the health plan or the UR company.

MAILING INSTRUCTIONS

Please mail your application for external review to:

Connecticut Insurance Department
P.O. Box 816
Hartford, CT 06142-0816

Attn: External Appeals

For overnight delivery only, please send your application for external review to:

Connecticut Insurance Department
153 Market Street, 7th Floor
Hartford, CT 06103

Attn: External Appeals

Please call (860) 297-3910 for additional copies of this brochure, or with any questions or concerns that you may have. This External Appeal Consumer Guide and the External Appeal Request form are also available on the State of Connecticut Insurance Department's web site: <http://www.ct.gov/cid>

**GLOSSARY**

A Health Plan is a Managed Care Organization or an insurance company from which you or your employer contracted health benefits.

A Managed Care Organization is an insurer, a health care center (HMO), or other entity that issues coverage through a managed care plan.

A Managed Care Plan is a product offered by a managed care organization that utilizes a network of providers and includes utilization review.

Medical Necessity refers to the medical appropriateness of health care services that are needed to meet basic health care needs, consistent with diagnosis of condition and rendered in a cost-effective manner, and consistent with the national medical practice guidelines regarding type, frequency and duration of treatment.

Utilization Review (UR) is the prospective or concurrent assessment and decision making process used to determine the necessity and appropriateness of the allocation of health care resources provided to or proposed to be given to an insured under a managed care plan.

Revised 8/13/2007



STATE OF CONNECTICUT – INSURANCE DEPARTMENT REQUEST FOR EXTERNAL APPEAL

Return to:

• P.O. Box 816 • Hartford, CT 06142-0816
• 153 Market Street • Hartford, CT 06103 (OVERNIGHT MAIL ONLY)
• (860) 297-3910

APPLICANT NAME _____ Enrollee/Patient Provider

ENROLLEE INFORMATION

Enrollee Name: _____ Patient Name: _____

Address: _____

Enrollee Phone #: Home () _____ Work () _____

Enrollee Insurance ID #: _____

Insurance Claim/Reference #: _____

PROVIDER INFORMATION

Health Care Provider: _____

Address: _____

Contact Person: _____ Phone: () _____

Medical Record #: _____

HEALTH PLAN (Managed Care Organization or Insurance Company)

Managed Care Organization: _____

Address: _____

Contact Person: _____ Phone: () _____

UTILIZATION REVIEW COMPANY (If different than the Health plan)

Utilization Review Company: _____

Address: _____

Contact Person: _____ Phone: () _____

***** PLEASE COMPLETE ALL PAGES OF THIS FORM ***** revised 6/13/2007

Enrollee/Patient Name: _____ Enrollee Insurance ID #: _____

DESCRIBE IN DETAIL THE DISAGREEMENT WITH THE HEALTH PLAN. INDICATE CLEARLY THE SERVICE(S) BEING DENIED AND THE SPECIFIC DATE(S) BEING DENIED. ATTACH ADDITIONAL PAGES IF NECESSARY AND INCLUDE PERTINENT MEDICAL RECORDS, IF AVAILABLE.

PLEASE CHECK BELOW (NOTE: YOUR REQUEST WILL NOT BE ACCEPTED FOR FULL REVIEW UNLESS ALL FIVE (5) ITEMS BELOW ARE INCLUDED*)

1. **YES**, I have enclosed a NON-REFUNDABLE check or money order for \$25 (Make payable to: Treasurer, State of Connecticut). [The filing fee will be waived for indigent individuals. Please see below, "Waiver of Filing Fee"];
2. **YES**, I have included a photocopy of my insurance identification card;
3. **YES**, I have enclosed the letter from my health plan or utilization review company that states that their decision is final and that I have exhausted all internal appeal procedures;
4. **YES**, I have executed the release of medical records [Please see below]. Dependent applicants (18 years and older) are responsible for signing the medical release form.
5. **YES**, I have enclosed proof that the service in question is a covered benefit. *Please check one of the following:*
 - A copy of my entire insurance policy benefit handbook or certificate of coverage, that defines all benefits and provisions with my health plan (Summary of Benefits is not acceptable) , OR,
 - A copy of instructions from the health plan on how to access an electronic version of the policy benefit handbook or certificate of coverage, OR,
 - A copy of a letter from the health plan certifying the service is a covered benefit, OR,
 - I have requested a copy* of my handbook/certificate of coverage from my health plan and have not yet received a response. Attached is a dated copy of the letter or e-mail requesting my handbook or certificate of coverage.

[If you do not have a Handbook or Certificate of Coverage, write or e-mail your health plan for a copy immediately. **DO NOT DELAY.** If you do not receive these documents prior to your 60 day deadline to submit this request, send this Request for External Appeal to the Insurance Department before the 60 calendar days expire. A copy of your written request to the health plan for the Benefit Handbook/Certificate of Coverage must be submitted with this Request for External Appeal.]*

***** PLEASE COMPLETE ALL PAGES OF THIS FORM ***** revised 6/13/2007



appeal. Your appeal will be rejected if all of these items are not included:

April 16, 2009

Dina B. Berlyn, Esq.
30 Morris Street
Hamden, CT 06517
Dina.berlyn@coa.ct.gov
dinaberlyn@yahoo.com
w-860-240-8629 c-203-530-2529
work fax 860 240 0208

To: Sonia Suelen 978 741 1990

From: Dina Berlyn

Re: 384170

As we discussed, I would be most appreciative of receiving a copy of the entire record in my case. In addition, I need either the benefits handbook or certificate of coverage.

Thank you.

Dina B Berlyn

Dina B. Berlyn

↓
I did not
get these

@ Caremark. com



April 14, 2009

Ms. Dina Berlyn
30 Morris Street
Hamden, CT 06517

Dear Ms. Berlyn:

CVS Caremark manages the prescription drug benefits for employees and dependents of The State of Connecticut.

This letter is in response to your recent request from **April 14, 2009**, for the internal rule, protocol or guideline that was used to determine the benefits regarding the medicine, **Provigil**.

Under the State of Connecticut Prescription Benefit Plan, Provigil is covered with Prior authorization. As such, Provigil is covered for patients who meet the following criteria:

- Narcolepsy confirmed by polysomnography
- Obstructive Sleep Apnea/Hypopnea Syndrome confirmed by polysomnography with respiratory monitoring and
 - the patient is currently utilizing continuous positive airway pressure (CPAP) therapy, or
 - CPAP therapy is contraindicated for the patient, or
 - CPAP therapy was tried and found to be ineffective for the patient even though the patient was compliant with therapy, or
 - the patient has mild obstructive sleep apnea/hypopnea syndrome, the patient uses an oral appliance and the patient is compliant with oral compliance use.
- Shift Work Sleep Disorder (SWSD)
 - The patient experiences sleepiness while working, and
 - The patient works the night shift (at least 5 hours between the hours of 11pm and 7am) permanently, or
 - The patient works the night shift frequently (5 times or more per month).



Our records show that your physician provided a diagnosis of Multiple Sclerosis related fatigue. This diagnosis does not meet the above criteria.

the prescription was for fatigue not MS dx

In addition, this case was forwarded to an outside medical reviewer for review at the first and second level of appeal. The physician reviewer at the first level of appeal stated "there are no randomized, double-blind, placebo-controlled studies supporting the use of Provigil for cognitive dysfunction in MS. Although Provigil may be of benefit in this patient for the treatment of her fatigue and cognitive dysfunction, it cannot be deemed medically necessary based on current medical literature."

At the second level of appeal, the physician reviewer stated, "the only peer reviewed study in the literature finds Provigil to be of no value for MS fatigue. Therefore, its use for this indication is unproven, investigational and not medically necessary." *WRONG. See Rammohan, Zifko, and Lange paper*

Based on this information, the clinical criteria for coverage of Provigil were not met, and it was not determined to be medically necessary by outside medical review. As a result, the request for coverage was denied.

If you have any further questions or comments about this matter, please contact CVS Caremark's Clinical Services Division toll-free at 1-800-952-9684.

Sincerely,

Clinical Services
CVS Caremark
Case 384170 / jar



April 09, 2009

DINA BERLYN
30 MORRIS ST
HAMDEN, CT 06517

Re: DINA BERLYN
Medication: PROVIGIL 100 MG TABLET
Provider: JANA PREININGEROVA, MD
Case Number: 384170

Dear DINA BERLYN:

CVS Caremark reviews the medical necessity of medications for State of Connecticut plan participants.

Our consultant, a board certified Neurologist, has reviewed the clinical information regarding this case. Based on the information provided, the prescription for PROVIGIL 100 MG TABLET has not been approved because:

The requested medication is not covered for the submitted diagnosis of Multiple Sclerosis related fatigue. The physician reviewer has contacted the Prescriber for further information regarding the diagnosis provided for this medication and has denied the request for coverage. The patient does not have an FDA approved indication for the use of Provigil. Therefore, its use for this diagnosis at this time cannot be supported by current medical literature.

All internal appeals have now been exhausted. However, you have the right to file an external appeal with the Insurance Commissioner. If you elect to do so, an appeal must be submitted in writing by you or your doctor, with your written consent, within 60 days of receiving this communication. You may contact the Connecticut Insurance Department by calling (860) 297-3910 or by writing to:

Connecticut Insurance Department
P.O. Box 816
Hartford, CT 06142-0816
Attn: External Appeals

Please note: The external appeals process is not available to enrollees who are covered under a non-governmental self-insured plan established pursuant to the Employee Retirement Income Security Act of 1974 (ERISA) or to denials regarding workers compensation.

This page may contain references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information.
91-15458d

External appeals will be determined within 30 business days of completing the preliminary review, at which time you will be notified.

You may request the applicable criteria, if any, used in this case by contacting CVS Caremark's Clinical Prior Authorization Department. If you have any questions or would like to talk with a Clinical Prior Authorization Representative, please call toll-free 1-800-952-9684.

Sincerely,

Clinical Services
CVS Caremark

cc: JANA PREININGEROVA, MD

Enclosures: External Appeal Consumer Guide, External Appeal Request Form



April 03, 2009

DINA BERLYN
30 MORRIS ST
HAMDEN, CT 06517

Re: DINA BERLYN
Medication: PROVIGIL 100 MG TABLET
Provider: JANA PREININGEROVA, MD
Case Number: 384170

*It was NOT
prescribed for
cognitive dysfunction!
It is for fatigue.
Cognitive dysfunction is
NOT mentioned in
my medical records
at all!*

Dear DINA BERLYN:

CVS Caremark reviews the medical necessity of medications for State of Connecticut plan participants.

Our consultant, a licensed physician, has again reviewed the clinical information regarding this case. Based on the information provided, the prescription for PROVIGIL 100 MG TABLET has not been approved because:

The requested medication is not covered for the submitted diagnosis of Multiple Sclerosis related fatigue. The physician reviewer has contacted the Prescriber for further information regarding the diagnosis provided for this medication and has denied the request for coverage. The patient does not have an FDA approved indication for the use of Provigil. There are no randomized, double-blind, placebo-controlled studies supporting the use of Provigil for cognitive dysfunction in MS. Therefore, its use for this diagnosis at this time cannot be supported by current medical literature.

*not prescribed for
Cog dys!*

You have the right to request another appeal. If you elect to do so, an appeal should be submitted in writing by you or your authorized representative within 180 days of receiving this communication. The appeal should identify any issues, comments or additional evidence to support your request and should include your medical record as it relates to this request.

For cases of an urgent nature, you may request an expedited appeal by calling 1-800-952-9684, faxing a written appeal to 1-800-230-0783 or mailing a written appeal with a copy of this letter to:

CVS Caremark Clinical Services
Clinical PA Department
P.O. Box 519
Lincoln, RI 02865

You may submit an appeal for any denial or limitation of a requested service by calling the Clinical Prior Authorization Department toll-free at 1-800-952-9684. You have the right to be represented by a person of your choice and can indicate this choice either verbally or in writing when starting the appeals process. Appeals are determined within 15 days of receipt of the request. An expedited appeal may be requested when a service is urgent in nature, and will be completed within 24 hours of receipt of all necessary information.

Once all internal appeals have been exhausted, you have the right to file an external appeal with the Insurance Commissioner. If you elect to do so, an appeal must be submitted in writing by you or your doctor, with your written consent, within 60 days of the final denial notice. You may contact the Connecticut Insurance Department by calling (860) 297-3910 or by writing to:

Connecticut Insurance Department
P.O. Box 816
Hartford, CT 06142-0816
Attn: External Appeals

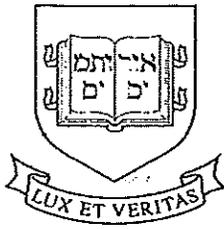
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Sincerely,

Clinical Services
CVS Caremark

cc: JANA PREININGEROVA, MD



Yale University School of Medicine

*Department of Neurology
40 Temple St 6C
New Haven, Connecticut 06510
203-785-4085
FAX: 203-785-4937*

March 26, 2009

Re: Dina ~~Beryln~~ Berlyn

DOB: 1/21/66

To Whom It May Concern:

This is an appeal for re-consideration of your denial of coverage of modafinil (Provigil) for my patient Dina Berlyn who has a diagnosis of relapsing-remitting multiple sclerosis. I write as both Ms. Beryln neurologist and as a specialist in the management of multiple sclerosis.

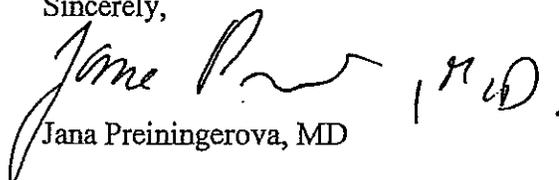
Fatigue is recognized by the National Multiple Sclerosis Society (NMSS) as the most common symptom of the disease, and is known to affect over three-fourths of all those living with MS. The diagnosis and management of MS-related fatigue is described in the Society's Clinical Bulletin "Management of Fatigue in Multiple Sclerosis", which is enclosed for your information. In a 2002 study to assess the efficacy and safety of modafinil for the treatment of fatigue in MS, Rammohan and colleagues found that 200 mg/day of modafinil significantly reduced fatigue and was well tolerated.

A review of Ms. Berlyn's medical history documents history of RRMS diagnosed in early 1997 and report of severe, debilitating fatigue and day time sleepiness dating back more than five years.

I believe continuation of treatment with Provigil is medically necessary and appropriate, and urge you to provide coverage of it as an off-label indication for her MS-related fatigue. If Provigil is discontinued her fatigue may result in preventable disability, inability to live independently or maintain employment, depression, immobility, muscle weakness, etc.)

I hope this information is helpful to you and others, and encourage you to contact me at (203) 785-4085 if I may be of further assistance.

Sincerely,


Jana Preiningerova, MD

Dina B. Berlyn, Esq.
30 Morris Street
Hamden, CT 06517
Dina.berlyn@cga.ct.gov
w-860-240-8629 c-203-530-2529

March 23, 2009

CVS Caremark Clinical Services
Clinical PA Department
P.O. Box 519
Lincoln, RI 02865

Dear Caremark:

This letter is my appeal of your unwarranted decision to deny coverage of Provigil (Modafinil) 100 mg. You have a lot of gall to think that it is ok for you to substitute your judgment for that of my treating physician. My physician, Dr. Jana Preingerova, is an MS specialist who also knows my specific case. MS is a very individualized disease and no two patients are the same; part of treating this disease has to be done by a sort of educated trial and error. Dr. Preingerova must be allowed to practice medicine and search for the best treatment regimen for each patient free of absurd encumbrances such as unjustified medication denials like this one. Perhaps you are unaware that fatigue is the most common (and quite debilitating) symptom of multiple sclerosis. Provigil is not the first drug that I have taken to fight fatigue but it is the first one that worked (I did not find amantidine helpful).

One of the excuses that I was given for the denial is that there are conflicting reports in the literature. In this situation, the decision must be made by the physician who has knowledge of the specific case. I did a quick literature search myself and found two articles supporting the use of Modafinil for MS patients (J. Neurol Neurosurg Psychiatry 2002 Feb;72(2):150 and J Neurol, 2002 Aug;249(8): 983-7). I found one article that did not find benefit but the article noted that the sample size in the study was extremely small (Drugs. 2008; 68(13): 1803-39). In Addition, I believe that a paper was presented at the European Committee for Treatment and Research in Multiple Sclerosis which demonstrated that the combination of Interferon-beta and Modafinil are effective at treating cognitive symptoms of MS.

Provigil has made it possible for me to continue in my job (counsel and executive aide to the majority leader of the state senate). If you intend to deny my access to the drug, do you plan to pay my salary and healthcare benefits? Before I took Provigil I found it nearly impossible to stay awake in the afternoon. Provigil has been a fantastic remedy for me. The only rational decision for you to make is to approve the prior authorization.

I would like to point out that your company has the worst customer service I have ever experienced. I was kept on hold for well over an hour over two days at one point. I know you only have records of me calling beginning March 7; I called earlier but no one would take my name. One of the people I talked to informed me that Caremark is not an insurance company and thus not bound by CT insurance law. That was not a smart statement. Perhaps the state legislature needs to take a look at the best way to regulate PBMs to prevent them from denying needed medication to patients. I was given all kinds of incorrect information by Caremark's customer service and the process was dragged out so long that I had to get samples from my doctor. **THE POLICY YOU SHOULD HAVE IS THAT IF YOU ARE GOING TO DENY A PERSON IN THE PRIOR AUTHORIZATION, YOU SHOULD APPROVE ONE MONTH'S SUPPLY TO GET THAT PERSON THROUGH THE APPEALS PROCESS. CONNECTICUT REQUIRES THIS FOR ITS MEDICAID MANAGED CARE ORGANIZATIONS!** In my case, because I screamed like a stuck pig to the Comptroller's office, I did get a call from Caremark and the denial was overridden for one month. But this should be your standard policy – not just special treatment for me because of who I know and where I work!!!

I honestly hope that you not only reverse your denial on appeal but also change your galling policies in which you inappropriately substitute your judgment for that of the treating physician. If you deny this appeal please realize that I will also pursue an external appeal with the Office of the Healthcare Advocate. That office is also well aware of your poor customer service.

I assume that none of you in the denial business have any family members who suffer from chronic incurable ailments. If you did you would not make decisions such as this one.

Thank you.

Dina Berlyn, Esq.

Addendum:

Because Caremark is performing a government function, I believe it must follow government rules in regard to transparency. Please forward to me:
% of state employee claims that are denied
% of state employee claims for Provigil that are denied
\$ Caremark receives from pharmaceutical companies that make Provigil competitors

→ then did not send this in



March 16, 2009

DINA BERLYN
30 MORRIS ST
HAMDEN, CT 06517

Re: DINA BERLYN
Medication: PROVIGIL 100 MG TABLET
Provider: JANA PREININGEROVA, MD
Case Number: 384170

Dear DINA BERLYN:

CVS Caremark reviews the medical necessity of medications for State of Connecticut plan participants. After careful review of the information provided, it has been determined that the request for PROVIGIL 100 MG TABLET does not meet medical necessity criteria because:

The requested medication is not covered for the submitted diagnosis of Multiple Sclerosis.

You have the right to appeal this decision. If you elect to do so, an appeal should be submitted in writing by you or your authorized representative within 180 days of receiving this communication. The appeal should identify any issues, comments or additional evidence to support your request and should include your medical record as it relates to this request.

For urgent cases, you may request an expedited appeal by calling toll-free 1-800-952-9684, faxing a written appeal to 1-800-230-0783 or mailing a written appeal with a copy of this letter to:

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Sincerely,

Clinical Services
CVS Caremark

cc: JANA PREININGEROVA, MD