

ASPEN MEDICAL BILLING ADVOCATES

The following was included with an appeal of the denial of prescription coverage for Provigil by a Medicare Part D plan with AARP Medicare Rx.

In this case, the appeal was successful, the denial was overturned, and the prescription was covered by the plan.

The document below applies only to a specific case and a specific set of facts and may or may not be applicable to other Medicare Part D appeals. However, since the appeal was immediately successful, in this case, it may serve as a model for other appeals.

Contact: Victoria Caras - Victoria@AspenBillingAdvocates.com

Re: Coverage rule exception request
Denial of Prescription coverage for Provigil for excessive fatigue and depression

The State of California Department of Managed Healthcare www.healthhelp.ca.gov regulates healthcare rights and assures that plan members receive benefits. Starting in 2001, it implemented an Independent Medical Review program (IMR). All IMR findings regarding the use of Provigil for depression and bipolar depression have been reviewed in considering the wrongful denial of coverage of Provigil.

In more than 25 cases, the IMR found that **Provigil was medically necessary in the treatment of depression and bipolar depression**, especially where a patient has been on a long regimen of Provigil, and responded well and consistently over time. In all of these cases, the **IMR has overturned the health care plan's denial of coverage**:

"The physician reviewer found that there are studies demonstrating the benefits of Provigil in the treatment of bipolar depression. Bipolar depression is often characterized by atypical features such as hypersomnia. There are no alternatives to Provigil, which is unique in its mechanism of action. Regarding the potential side effects, psychostimulants are more often associated with switching from depression to mania than is Provigil. The submitted clinical evidence documents that this patient has significant psychiatric impairment and made a serious suicide attempt prior to her recent regimen. Since she was doing well on her recent protocol (including Provigil), it is medically appropriate and indicated for her to continue to receive Provigil." Reference ID #MN09-9960

"The use of a psychostimulant to augment treatment of antidepressants is well-established. Provigil has benefitted this patient, and he has demonstrated a specific need for Provigil to reduce and maintain his depressive symptoms." Reference ID #MN08-8627

PO BOX 8926 ASPEN COLORADO 81612
970.379.2292

VICTORIA@ASPENBILLINGADVOCATES.COM
WWW.ASPENBILLINGADVOCATES.COM

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An IMR overturned a denial of Provigil where the psychiatrist “*detailed the previous medication regimens and the patient’s response in regard to depression and lethargy/inertia. The patient has responded well to Provigil and continued treatment should be supported.*” Reference ID# MN07-7418

In two additional instances the IMR overturned a denial of Provigil where “*the physician reviewer overturned the Health Plan’s denial on the basis that the requested medication is medically necessary.*” Reference ID # MN03-1381, MN03-1382, MN03-3287

These cases specifically apply. The patient has a long history (5+ years) of success on Provigil. It has been uniquely successful for her with no problems, side effects or other symptoms. Continuing on Provigil is entirely indicated.

By contrast, **none of the cases where the denial of Provigil was upheld apply.** They are cases of polypharmacy, multiple disorders, a lack of continued success in the patient, co-morbidity, etc. In fact, **there is no case in the nine-year history of the IMR where a patient with a long history of success and stability on Provigil was denied.**

Multiple accredited research studies support the use of Provigil for both depression and bipolar depression:

“... *adjunctive modafinil at doses of 100-200 mg a day may improve depressive symptoms in patients with bipolar disorder*” Department of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine, UCLA

“*It may be that a symptomatic rather than a hypothesis-bound mode of thinking is the best way for a clinician to help a patient with bipolar depression.*” R.H. Belmaker, MD, American Journal of Psychiatry, August 2007

That finding is exactly the case here; the patient’s symptoms indicated Provigil, which, once tried, has been effective for significant duration. Not only is there no other drug indicated, a change in regimen is in fact contraindicated.

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