DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-1011

In the case of	**Claim for**
K.M. (Appellant)	Prescription Drug Benefits (Part D)
**** (Enrollee)	**** (HIC Number)
AARP Medicare Complete Secure Horizons Plan 2 (Part D Plan)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated March 22, 2012, which concerned the enrollee's request for Medicare Part D coverage for the prescription drug Strattera (Atomoxetine Hydrochloride), 60 mg capsules (one 60 mg capsule daily). The ALJ determined that the Part D prescription drug plan (Part D plan) was not required to cover and pay for the prescription drug Strattera for the enrollee. The appellant enrollee, represented by her psychiatrist, has asked the Medicare Appeals Council (Council) to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 423.2108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the enrollee in the request for review, unless the enrollee is unrepresented. 42 C.F.R. § 423.2112(c). The enrollee's request for review is hereby made a part of the record as Exhibit (Exh.) MAC-1. The April 4, 2012 letter from the enrollee's psychiatrist (Dr. S.B.), explaining that the psychiatrist has formally diagnosed the enrollee with attention deficit hyperactivity disorder (ADHD), is hereby made a part of the record as Exh. MAC-2.

Section 423.2122(a)(1) of the Medicare Part D regulations states that the Council will consider the evidence contained in the

record of the proceedings before the ALJ, and any new evidence that relates to the period before the coverage determination. The treating psychiatrist's April 4, 2012 letter, explaining her ADHD diagnosis of a longstanding and continuing condition, relates to the beneficiary's condition both before and after the coverage determination. It contains and explains the diagnosis of one of the enrollee's existing and ongoing conditions (ADHD). Therefore, the Council enters it into the record and considers it in rendering this decision.

The enrollee has also asked for expedited review, which the Council grants pursuant to the provisions in the Medicare Part D regulations at 42 C.F.R. § 423.2108(d).

For the reasons set forth below, the Council reverses the ALJ's decision, and decides that the Part D plan must cover the prescription drug Strattera for the enrollee.

BACKGROUND

The enrollee is diagnosed with bipolar disorder and has a history of significant symptoms since the late 1990s, including periods of severe depression and episodes of mania, sometimes with psychosis. Exh. 2 (Psychiatric Closing Report from Carson Center in Massachusetts, December 14, 2009; *also* February 13, 2012 Letter from Dr. S.B. to AARP Medicare Complete Secure Horizons).[1] At some points during the last fifteen years, the enrollee required hospitalization for mental health problems, and had at least one trial of ECT (electroconvulsive or electroshock therapy). *Id.* She also has difficulties with mental focus, concentration, and attention, and possibly a learning disability. *Id.; see also* Exh. 5 (February 29, 2012 Letter from Dr. S.B. to Maximus Federal Services; *also* February 27, 2012 Letter from Enrollee to M.J.A., Chief Pharmacy Officer, United Healthcare) (Enrollee Letter).

The enrollee has had trial periods with numerous medications to address her mental health problems; many of the medications were ineffective or had problematic effects and side effects. Dr. A.S., at the Carson Center in Massachusetts, developed a three drug regimen (including Strattera) enabling the beneficiary to

[1] The medical and procedural record in this case has been organized into five exhibits; however, the pages within some of the exhibits have not been numbered. *E.g.,* Exhibits 2, 5. For that reason, the relevant documents within the exhibits that have not been numbered are briefly described in parentheses with each citation to the record.

stabilize her mood disorder and better focus, concentrate, and attend to tasks at hand. Exh. 5 (Dr. S.B. Letter); Exh. 2 (Psychiatric Closing Report and Medication Chart for 9/15/2006 through 3/26/2007 (Medication Chart)). When the enrollee moved from Massachusetts to Colorado in early 2010, Dr. S.B. became her treating psychiatrist and continued the same medications that Dr. A.S. had prescribed, with positive results. Exh. 5 (Dr. S.B. Letter).

The enrollee has had unsuccessful trial periods using, first, Adderall and then Ritalin in her medication regimen. Exh. 2 (Medication Chart). As Dr. S.B. explained after reviewing the enrollee's medical records:

> [The enrollee] was unable to tolerate central nervous system stimulants [e.g. Adderall and Ritalin] because they destabilized her mood, creating mood elevation and disinhibition. It is not uncommon for bipolar patients to have difficulty tolerating central nervous system stimulants; although, some patients are able to do so without difficulty. Clearly [the enrollee] is one of the patients who cannot tolerate central nervous system stimulants because of adverse/counterproductive mood effects. Strattera helped her mental focus, concentration, and attention without destabilizing her mood. Given the pharmacology of Strattera, this makes sense.

Exh. 5 (Dr. B.S. Letter at 2); *see also* Enrollee Letter at 1. Dr. S.B.'s letters and reports indicate that she is board-certified in psychiatry and neurology. *See, e.g.,* Exh. 2 (Dr. S.B. Letter).

In the enrollee's letter, she reports that since she began taking Strattera, it has required a prior authorization every year and has always been approved. Exh. 5 (Enrollee Letter at 1).[2] On February 14, 2012, the current Part D plan denied the enrollee coverage of Strattera, on the ground that it is not Food and Drug Administration (FDA) approved for the treatment of bipolar I disorder, nor is it listed for the treatment of bipolar I disorder in the Medicare approved compendia. Exh. 2 (February 14, 2012 Notice of Denial of Medicare Prescription Drug Coverage). On redetermination by the plan, coverage was again denied on the same basis. Exh. 3. On March 1, 2012, the

[2] The record does not indicate whether the prior approvals for this medication came from the same plan, or a different plan or insurer.

Part D Qualified Independent Contractor (Part D QIC) also denied coverage on the same basis. Exh. 4.

The ALJ granted expedited consideration, and held a hearing on March 21, 2012, at which Dr. S.B. represented the beneficiary. The ALJ acknowledged that Strattera is FDA-approved for ADHD, but not bipolar disorder, and that the medical records "recorded symptoms consisted [sic] with ADHD though it was not an actual diagnosis." The ALJ denied coverage on the same ground as previously, because the prescription drug Strattera has not been approved by the FDA or listed in the Medicare approved compendia for the off-label treatment of bipolar disorder. Dec. at 1-5.[3] This expedited appeal followed.

DISCUSSION

With her request for review on behalf of the enrollee, the enrollee's psychiatrist submitted an additional letter or signed statement, dated April 4, 2012. Letter from Dr. S.B. to the Medicare Appeals Council, dated April 4, 2012. The psychiatrist writes that her earlier letter (dated February 29, 2012) provided details of the enrollee's mood disorder and difficulties with mental focus, concentration and attention. The psychiatrist reiterates that Strattera 60 mg. addresses the enrollee's mental focus, concentration and attention problems, and that the enrollee cannot tolerate central nervous system (CNS) stimulants such as Ritalin, Dexedrine and Adderall. In fact, the psychiatrist points out, these CNS stimulants, used during earlier trial periods, de-stabilized the enrollee's mood, creating problems with mood elevation and dis-inhibition.

Next, the letter explains that as the enrollee's treating psychiatrist, Dr. S.B. has formally diagnosed the enrollee now with attention deficit hyperactivity disorder (ADHD) (as well as bipolar disorder):

> Perhaps it was an oversight on my part to describe her symptoms and not expressly state a diagnosis of attention deficit hyperactivity disorder for [the enrollee]. She and I have met and I have taken a careful historical review of her symptoms over time. A diagnosis of attention deficit hyperactivity disorder has been made and has been filed

[3] The ALJ's decision refers to another MA plan's (Medco) Evidence of Coverage. *See* Dec. at 3, Section II.B. We assume this reference was inadvertent error.

> with her insurance company along with the existing diagnosis of bipolar I disorder.

Letter from Dr. S.B. to the Medicare Appeals Council, dated April 4, 2012.

As Dr. S.B. states, she has performed a detailed review of the enrollee's mental health records from Massachusetts, and has interviewed the enrollee her about her current symptoms and her symptoms over several years. In addition, Dr. S.B. has first-hand knowledge of the enrollee's conditions and symptoms from treating her from May 2010 to the current date.

Based on the medical and mental health records submitted, the Council finds the statements in the Dr. S.B.'s letters credible, and her opinions useful in determining that the beneficiary has been diagnosed with ADHD (as well as bipolar disorder). Therefore, the drug Strattera, as prescribed by Dr. S.B., is reasonable and necessary for the enrollee's treatment.

In addition, the Council notes that according to the Part D plan's formulary information (contained in the record), Strattera may be approved if an enrollee has tried an ADHD stimulant: amphetamine/dextroamphetamine combination or dextroamphetamine or methylphenidate or dexmethylphenidate. Exh. 3 (screen print, Part D and UHG Hybrid – Formulary Lookup). In this case, as noted above, the record documents that the enrollee tried both Adderall and Ritalin under psychiatric supervision in 2006 and 2007, with serious adverse effects. Exh. 2 (Medication Chart); Exh. 5 (Dr. S.B. Letter at 2; Enrollee Letter at 1). Given the serious adverse effects of the earlier trial, such a trial of a CNS stimulant should not be repeated for coverage (as opposed to medical) purposes.

DECISION

The Medicare Appeals Council reverses the ALJ's decision, determining that the Medicare Part D prescription drug plan is required to cover the prescription drug Strattera for the

enrollee, starting with the date of her recent ADHD diagnosis by Dr. S.B.[4]

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: April 10, 2012

[4] This starting date can be either the date of Dr. S.B.'s April 4, 2012 letter to the Medicare Appeals Council, or the date when Dr. S.B. notified the beneficiary's Part D plan of her ADHD diagnosis.