

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

**DECISION OF MEDICARE APPEALS COUNCIL**  
**Docket Number: M-13-2627**

**In the case of**

**Claim for**

J.R.

Prescription Drug Benefit  
(Part D)

\_\_\_\_\_  
(Appellant)

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\_\_\_\_\_  
(Enrollee)

\_\_\_\_\_  
(HIC Number)

Anthem Insurance Company /  
Blue Medicare Rx

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\_\_\_\_\_  
(Part D Plan/Part D Sponsor)

\_\_\_\_\_  
(ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated May 17, 2013, because there is an error of law material to the outcome of the claim. See 42 C.F.R. § 405.1110. The ALJ issued a fully favorable decision directing the Medicare Part D prescription drug plan (plan) in which the beneficiary was enrolled, to grant a tiering exception, from tier 5 to a tier 4, for modafinil 200mg (brand name Provigil) for the 2013 plan benefit year. Further, the ALJ directed the plan to reimburse the enrollee for the "excess copayments" that she was required to pay for the drug at issue prior to the ALJ's decision.

By memorandum dated July 11, 2013, Maximus Federal Services, the Medicare Part D Qualified Independent Contractor, acting as the Independent Review Entity (IRE), asked the Council to review the decision on its own motion pursuant to 42 C.F.R. § 423.2110(b). The Council enters the memorandum, with attachments, into the administrative record as exhibit (Exh.) MAC-1. A copy of the IRE's referral memorandum was previously furnished to the enrollee and the plan. The Council has received no response from the enrollee to the referral memorandum.

The Council has carefully considered the record that was before the ALJ, as well as the IRE's memorandum. For the reasons explained in more detail below, the Council finds that the ALJ was without the authority to grant a tiering exception for the enrollee's modafinil under the circumstances of this case. WE further find that there is no other legal authority which supports the ALJ's decision to alter cost-sharing. Therefore, the Council reverses the ALJ's decision.

#### BACKGROUND

The record indicates that, at the time of the enrollee's initial request for a tiering exception, she had diagnoses of narcolepsy, depression and chronic obstructive sleep apnea with residual mood, cognitive and functional impairments for which she was being treated with modafinil. Exh. 4 at 14, Exh. 6 at 1. In 2012, the plan in which the enrollee participated, Blue Medicare Rx, administered by Anthem, classified modafinil as a tier 1 generic drug which required prior authorization and quantity limits. *Reference* Hearing CD at 13:25:06-13:27:55. The record indicates that the plan approved the enrollee's request for preauthorization of coverage of modafinil from June 21, 2012, through September 19, 2013. Exh. 1 at 10. Upon attempting to refill her prescription in calendar year 2013, the enrollee became aware that the plan moved modafinil from tier 1 to tier 5. Exh. 5 at 5; *reference also* Hearing CD at 13:27:56-13:30:58. The enrollee then requested that an exception be made to the plan's tiering designation which made her modafinil cost prohibitive. *Id.*

Initially and upon redetermination, the plan denied the enrollee's request for a tiering exception stating that "the requested drug is on the specialty tier of [the plan's] formulary. [The plan] does not allow exceptions to provide drugs in this tier at a lower copay or coinsurance." Exh. 4 at 1. Upon further appeal, the IRE upheld the plan's denial of a tiering exception for modafinil. Exh. 5 at 2. The IRE explained that Medicare rules do not require a plan to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs. *Id.*

The enrollee then requested an ALJ hearing, and the ALJ found that the plan failed to notify the enrollee in writing that modafinil would be subject to a tiering change for the 2013 plan year pursuant to 42 C.F.R. §§ 423.120(b)(5) and (b)(6). ALJ Decision (Dec.) at 4-5. The ALJ further found that the enrollee

relied to her detriment on the plan's preauthorization approval that stated she would be allowed the drug until September 2013. *Id.* For these reasons, the ALJ directed the plan to provide the enrollee coverage for modafinil as a Tier 4 drug for the remainder of 2013, and ordered the plan to reimburse the "excess copayments she was required to pay" prior to the issuance of decision. *Id.* at 5.

On July 11, 2013, the IRE referred the ALJ's decision for own motion review by the Council, stating that the ALJ committed "errors of law material to the outcome of the case." Exh. MAC-1 at 1. The IRE contends that the ALJ erred in granting the enrollee a tiering exception for modafinil because—

- it is a "specialty tiered drug and therefore not eligible for a tiering exception," (*id.* at 4-6);
- basing a tiering exception on the principles of estoppel is a material legal error, (*id.* at 6-8); and
- lack of notice of a tier change is neither an appealable issue nor a basis upon which to grant a tiering exception, (*id.* at 8-9).

#### **LEGAL AUTHORITIES**

The regulations governing tiering exceptions are found in 42 C.F.R. § 423.578. They provide, in pertinent part:

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS's approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement . . . .

\* \* \*

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-

sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

### DISCUSSION

We have carefully considered the record. As detailed below, we find that there is no legal authority to change the enrollee's cost-sharing from tier 5.

For calendar year 2013, the plan lists modafinil as a tier 5 drug. See Blue Medicare Rx 2013 Formulary, Exh. 7 at 88, (back of page.) In section 5.3 of the 2013 Blue Medicare Rx Explanation of Coverage (EOC) manual, designated "What can you do if your drug is in a cost-sharing tier you think is too high," the plan explains that—

[d]rugs in some of our cost-sharing tiers are not eligible for [an] exception. [The plan] does not lower the cost-sharing amount for drugs in Tie 1 (Preferred Generic Drugs), Tier 3 (Preferred Brand Drugs) or Tier 5 (Specialty Tier Drugs).

See Blue Medicare Rx 2013 EOC, Section 5.3, Exh. 7 at 52, (front and back of page); see also 42 C.F.R. § 423.578(a)(7). Thus, the enrollee is not eligible for a tiering exception, *per se*.

During the hearing, the enrollee testified as to her decision to continue participation in the plan. *Reference* Hearing CD at 13:27:56-13:30:58. The ALJ stated that "the [enrollee] understandably took [the notice of the plan's preauthorization of modafinil through September 2013] to mean that coverage for this drug would continue through the time period noted, under the same circumstances and with the same payment rate." Dec. at 4. The ALJ apparently alludes to the principles of estoppel in suggesting that the enrollee acted in reliance upon the plan's preauthorization statement in granting a tier exception. The IRE contends that the ALJ's reliance on estoppel, an equitable doctrine, is an error of law. Exh. MAC-1 at 2, 6-8.

As recounted in detail in the IRE's referral memorandum, the applicable federal case law provides that estoppel may not be invoked to require a government agency to allow the monetary payment of benefits that is not permitted by law. Exh. MAC-1 at 6-8 (citing *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990); *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51 (1984); *Schweiker v. Hansen*, 450 U.S. 785 (1981)). Like the ALJ, the Council is sympathetic to the enrollee's position in this case. Nonetheless, the Council agrees with the IRE that the ALJ essentially applied the principles of equitable estoppel to grant a tiering exception, allowing the enrollee to pay a lesser amount as a copayment for a drug classified in tier 5, a specialty tier. Simply put, the Medicare prescription drug program does not allow a tiering exception in this case; estoppel may not be invoked to compel the plan to reduce the copayment for a drug in a specialty tier. Thus, neither the ALJ nor the Council has authority to require the plan to limit its cost sharing charge for modafinil or to order reimbursement for any overpayments with respect to this case.

In addition, an enrollee's request for a tiering exception is a coverage determination subject to the administrative appeals process. 42 C.F.R. § 423.566. Grievance procedures apply to actions that are not coverage determinations, such as a plan's failure to give written notice of tiering change. 42 C.F.R. §§ 423.560, 423.564(b); see also Blue Medicare Rx 2013 EOC, Section 7.2, Exh. 7 at 59, (back of page.) Even if the plan had failed to give the enrollee proper notice of the tiering change for the drug, the adequacy of notice is an issue that is addressed through the plan's grievance procedures, and not through the administrative process, as the IRE argues. See Exh. MAC-1 at 8-9. Thus, the Council also finds that the ALJ erred by granting a tiering exception based on the enrollee's attestation that she did not receive direct written notice that the plan was implementing a tiering change for modafinil for 2013. Dec. at 4-5; reference also Hearing CD at 13:30:59-13:33:29.

Finally, the regulation cited by the ALJ as authority for requiring notice of a formulary change, 42 C.F.R. § 423.120(b)(5) and (6), applies only to changes within a plan year. In this case, the plan changed the formulary from one year to the next, not within a plan year. The 2013 formulary, which was available to the beneficiary, clearly lists modafinil as a tier 5 drug. Exh. 1 at 88. Any preauthorization of

coverage in 2012 through September 2013 does not preclude the plan from changing the drug tier when the plan year changes. Moreover, the appellant does not even request that the plan charge the same tier 1 cost-sharing in 2013 as she paid in 2012, but instead simply asks for less costly tier 4 cost-sharing.

#### **DECISION**

As enumerated above, neither the ALJ nor the Council have the authority to require the plan to furnish a tiering exception and reimburse the enrollee for any additional coinsurance she paid for modafinil thus far in plan year 2013. Accordingly, the ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki  
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair  
Departmental Appeals Board

Date: September 20, 2013