DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-1544

In the case of	**Claim for**
J.S. (Appellant)	Prescription Drug Benefits (Part D)
**** (Enrollee/Beneficiary)	**** (HIC Number)
Medica Health Care Plans (Part D Plan)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated April 30, 2012, concerning the enrollee's request for Medicare Part D coverage of Percocet® 5/325 mg. (Percocet) (generic name: oxycodone/acetaminophen). The ALJ denied coverage on the grounds that Percocet was not a medication covered by the enrollee's Part D plan and the enrollee's physician had not documented that Percocet was a medically reasonable and necessary exception to the Part D plan's formulary needed to treat the enrollee's condition.

The regulations at 42 C.F.R. § 423.2100 *et seq*. provide that an enrollee who is dissatisfied with an ALJ hearing decision concerning Medicare Part D prescription drug benefits may request that the Council review the ALJ's decision. The Council reviews the ALJ's decision *de novo*. 42 C.F.R. §§ 423.2100(b), 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 has been entered into the record as Exhibit (Exh.) MAC-1. Having considered the record

and the contentions, the Council concludes that there is no basis for changing the ALJ's decision and, accordingly, adopts the ALJ's decision.

DISCUSSION

The enrollee's pertinent medical history includes chronic back pain related to a herniated lumbar disc. Prior to the dates at issue here, the enrollee states that he received coverage for this drug, and the record reflects that the enrollee had been taking the drug since at least April 2011. Exh. 4, at 20.[1] The enrollee's Part D prescription drug plan (PDP) denied the enrollee's request for coverage of Percocet on February 14, 2012, finding that the enrollee's physician did not provide the necessary supporting documentation. Exh. 6, at 23. The PDP upheld the denial on the grounds that "medical necessity was not met / alternatives available on formulary." Exh. 8, at 31.

The enrollee sought reconsideration by an Independent Review Entity (IRE). The IRE denied coverage, following physician review. Exh. 9, at 38-39. The IRE noted that a PDP must grant an exception for a drug that is not on its formulary whenever it determines that the drug is medically necessary, consistent with the prescriber's statement, and that the drug would be covered but for the fact that it is not on the formulary. However, in order to grant such an exception, the statement must show that all of the covered drugs on any tier of the plan's formulary for treatment of the enrollee's condition would not be as effective as the non-formulary drug or would have adverse effects for the enrollee. *See* 42 C.F.R. 423.578(b). The IRE noted that the beneficiary was intolerant to the generic form of the drug and that the brand name drug had been effective and well tolerated in the past. However, the IRE denied coverage on the grounds that the enrollee did not meet the exceptions criteria because the prescribing physician did not state why the alternative formulary drugs were likely to be unsafe or ineffective. Exh. 9, at 39.

On further appeal and in the decision which followed, the ALJ set out the applicable Part D legal authorities, including the regulations pertaining to the formulary exceptions process. Dec. at 3-9. The ALJ noted that the appellant testified that the generic equivalent drug (oxycodone/acetominophen) made him sluggish and lethargic and that he did not want to take

[1] While it is not clear from the record, it appears that the prescription drug plan may have covered the drug in 2011 but dropped it from the formulary beginning January 1, 2012.

Oxycontin, another formulary drug, because of its addictive properties. However, the ALJ noted that the documentation did not demonstrate why other formulary drug alternatives in the same class of drugs, such as Vicodin, Codeine, or Fentanyl, would be ineffective or contraindicated for the enrollee. Dec. at 9. Thus, the ALJ found that the enrollee was not entitled to a formulary exception for Percocet.

In his request for review, the enrollee argued only that he needs this medicine to properly function on a daily basis and that he is willing to send an MRI on DVD to the Council, if requested. Exh. MAC-1.

The Council has reviewed the medical records, the applicable Medicare regulations and provisions, and the contentions of the enrollee. For purposes of this decision, the Council will not quote the relevant regulatory provisions for Medicare Part D formulary exceptions, as the ALJ has already done so extensively in his decision. The Council finds that the enrollee has not established that he qualifies for a formulary exception for Percocet. The beneficiary has explained that the generic version of the drug at issue is contraindicated for him and that he is reluctant to take Oxycontin. Nonetheless, he has not provided evidence from his physician that each of the formulary drugs in the category of autonomic and central nervous system medications/class II and III narcotics, of which there are twelve pages of such drugs on Medica Healthcare Plans' formulary, is either ineffective or contraindicated. *See* exh. 2. Without such indication from his physician, the enrollee does not qualify for a formulary exception for Percocet.

The Council has no reason to doubt that the enrollee has chronic back pain and needs pain medication. However, without any indication that either the enrollee has tried each of the other similar pain medications on the plan's formulary, or that his physician has considered and ruled out such medications on the basis that they would be less effective than Percocet or likely to cause harm to the enrollee, the Council may not grant a

formulary exception. Thus, it is not necessary for the enrollee to provide the Council with the MRI, as offered.

The Council therefore adopts the ALJ decision.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

Date: June 05, 2012