Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Western Field Office
Irvine, CA

Appeal of:	**L. Bornstein**	ALJ Appeal No.:	**1-2746519934**
Beneficiary:	**Same**		**Medicare Part D**
HICN:	**XXX-XX-5378A**	Before:	**James M. Takos** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a Fully Favorable decision is entered for Appellant/Beneficiary[1], L. Bornstein. The Appellant's Medicare Part D Prescription Drug Plan ("Plan"), Humana Insurance Company of New York, shall provide the Appellant with the prescription drug coverage for the drug, Nexavir vial 280/90 for the year 2014.

Procedural History

The Appellant requested her Part-D drug plan, to authorize coverage of NEXAVIR vial, 280/90 for her use in treatment of chronic fatigue syndrome (CFS). The Plan denied the request, and on appeal, affirmed the denial, stating that the drug is not an approved FDA drug product. (Exh, 5). The Appellant appealed the Plan's decision to Maximus Federal Services ("Maximus"), a Medicare contractor that handles Part D appeals. On March 29, 2014, Maximus issued both a dismissal and an unfavorable decision in one decision. The Appellant requested a hearing with an ALJ. A copy of the QIC's decision did not remain in the case file. On July 28, 2014, the ALJ issued a order remanding the appeal to the QIC to correct or clarify the information relating to its reconsideration decision so that the ALJ could hold a hearing and render a decision, if necessary.

[1] The Appellant is also the Beneficiary in this appeal. For purposes of brevity, he shall be referred to exclusively herein as 'the Appellant'.

(Exh. 8). The QIC reopened the case and issued a new unfavorable decision on October 2, 2014, vacating the previous dismissal. The QIC held that Medicare Part D does not cover drugs that are not FDA approved. The Plan determined that NEXAVIR is not FDA approved by checking FDA sources during the Reconsideration appeal and Reopening appeal. The QI affirmed its previous unfavorable decision regarding coverage of NEXAVIR. It did not address the medical necessity or appropriateness of the requested drug. (Exh. 9).

The Appellant filed a timely appeal on November 29, 2014 with the Office of Medicare Hearings and Appeals ("OMHA"), and requested review of its claim by an Administrative Law Judge ("ALJ"). The amount in controversy meets the jurisdictional requirement; therefore, there is jurisdiction to hear this matter.

On February 19, 2015, an administrative hearing was conducted telephonically from Irvine, California, on the Appellant's claim. Present was the Appellant, representing herself. Also present were Dr. Myrnes, and Mr. Brandon Howard, representing the Health Plan, Humana. The witnesses were sworn in under penalty of perjury, and Dr. Myrnes was found duly qualified to testify as a medical expert. All exhibits were entered into the record without objection. This decision follows.

Issue

The issue on appeal is whether the Part D Drug Plan is required to provide coverage to the Appellant for NEXIVIR under the regulations governing Medicare.

Findings of Fact

The evidence of record established the following facts by a preponderance of the evidence:

(1) The Appellant has used Nexavir continuously since December, 2009, for successful treatment of chronic fatigue syndrome. The drug , which was prescribed by Dr. Susan Levine, has been essential to maintain her health and quality of life. Testimony- hearing CD, and Exh. 9, pg. 66.

(2) Nexavir was covered under the Appellant's private insurance Plan through her former employer until she became eligible for Medicare. Prior to enrollment in a Medicare Health Plan, the Appellant researched which plan would cover Nexavir. The record established that Nexavir is bioidentical to Kutapressin, and has been used to treat a variety of conditions for almost 70 years, and is widely regarded as safe. (Exh. 1, pg. 17 et seq).[2] The Appellant tried other medications which were not effective. Her physician prescribed Nexavir, with dramatic results. (Exh. 9, pg. 58). Thus, the medical necessity of the drug is documented by the Appellant's physician in a letter dated August 23, 2013, as well as her testimony. Her primary physician also documented the need for this drug, stating that Nexavir has been found to have in vitro activity against EBV

[2] "Living With Chronic Fatigue Syndrome";
http://livingwithchronicfatiguesyndrome.workdpress.com/2010/1025/nexvir-kutapressin-for-cfs/

and HHV-6 and is therefore used in the treatment of CFS patients who test positive for this virus. *Id.* at pg. 57.

(3) The Plan has denied the Appellant's request for coverage of Nexavir, on the basis that the drug is not an FDA drug.

(4) The Appellant relied on the Plan's documented representation and its 2014 EOC, prior to enrollment, that Nexavir was included in its family of Formulary drugs. Based on the information she obtained from the Plan, the Appellant thought the drug would be covered. The Plan's Drug Tiers for 2012, 2013, and 2014, all include Nexavir in the EOC, as a Tiered drug. No discrimination is detailed in the EOC with regard to whether the drug is FDA approved or not. (Exh. 1, pgs. 2, 11, and Exh. 9, pg. 18-19).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In order to provide hearings to Appellants, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals (OMHA). See 70 Fed. Reg. 36386, 36387 (June 23, 2005). The Administrative Law Judges (ALJs) within OMHA issue the final decisions of the Secretary, unless those decisions are later reviewed by the Medicare Appeals Council. Id.

B. Scope of Review

The ALJ considers all of the issues brought out on a claim in the initial determination, any redetermination, or the reconsideration that were not decided entirely in a party's favor. See § 405.1032(a). In addition, the ALJ may consider issues that were favorably decided in the initial determination, any redetermination or the reconsideration if the ALJ provides notice that the issues will be considered at the hearing. See 42 C.F.R. § 405.1032(a)-(b).

The ALJ may decide the case without holding a hearing and without prior notice to the parties if the evidence supports a finding in favor of the appellant on every issue. See 42 C.F.R. § 405.1038(a). In addition, the ALJ may decide a case without holding a hearing if all parties indicate in writing that they do not wish to appear at the hearing, or the appellant lives outside of the United States and does not inform the ALJ that he or she wishes to appear, and no other parties wish to appear at the hearing. See 42 C.F.R. § 405.1038(b).

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue. See 70 Fed. Reg. 36386 (June 23, 2005). A de novo review means the ALJ reviews the evidence without regard to the findings in the prior determinations on the claim and makes an independent assessment based on the evidence and the controlling laws. However, the burden of proving each element of a Medicare claim lies with the Appellant and is satisfied by submitting sufficient evidence in accordance with Medicare rules. See e.g., Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; see also 42 C.F.R. § 424.5(a)(6), 42 C.F.R. §§ 405.1018, .1028, .1030.

An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. See 42 C.F.R. § 405.1018. See also 42 C.F.R. §§ 405.1028 and 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries.

I. Principles of Law

A. Statutes and Regulations

Section 101(a) of the Medicare Modernization Act of 2003 (PubLNo 108-173) establishes a voluntary prescription drug benefit under Part-D of the Social Security Act ("Act").

Section 1860 D-2(e) of the Act defines a covered Part-D drug as any of the following, if used for a medically accepted indication: (1) a drug that may be dispensed only upon a prescription; (2) a biological product; insulin; medical supplies associated with the injection of insulin; or an appropriately licensed vaccine.

Section 1927((k)(6) of the Act defines the term "medically accepted indication" as any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i). The following compendia are listed in Section 1927 (g)(1)(B)(i): the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information; and the DRUGDEX Information System.

42 Code of Federal Regulations ("C.F.R.") § 423.128(b) provides that Medicare Part-D plans must disclose to each enrollee of the Part-D plan information about its prescription drug plan concerning the plan's service area, the benefits offered under the plan, including applicable conditions and limitations, premiums, cost-sharing (e.g. co-payments, deductibles and coinsurance) and any other conditions associated with receipt or use of benefits.

42 C.F.R. § 423.578 provides that 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.

42 C.F.R. § 423.578(a) provides that a Part-D plan sponsor must grant a tiering exception involving a formulary approved drug whenever it determines that a non-preferred drug for treatment of an enrollee's condition is medically necessary.

42 C.F.R. § 423.578(a)(4)-(5) explains that in order to justify a tiering exception a prescribing physician must provide an oral or written statement that the preferred drug for the treatment of the enrollee's condition: (1) would not be as effective for the enrollee as the requested drug; or (2) would have adverse effects for the enrollee. Additionally, the Part-D plan may require the prescribing physician to provide additional supporting medical documentation establishing the enrollee meets the tiering exception requirements.

42 C.F.R. § 423.578(b) provides that a Part-D plan sponsor must grant a coverage exception for an off-formulary drug whenever it determines that the drug is medically reasonable and necessary for treatment of an enrollee's condition and would be covered but for the fact that it is not listed on Part-D plans drug formulary.

42 C.F.R. § 423.578(b)(5)-(6) explains that in order to justify an off-formulary exception, a prescribing physician must provide an oral or written statement that the requested drug is medically reasonable and necessary for the treatment of the enrollee's condition because: (1) all of the covered Part-D drugs on any tier of the plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug; or (2) would have adverse effects on the enrollee. Additionally, the Part-D plan may require the prescribing physician to provide additional supporting medical documentation establishing the enrollee meets the off-formulary exception requirements.

Analysis

The instant claim concerns the Plan's refusal to grant coverage authorization to the Appellant for use of the drug, Nexavir continuously since December, 2009, for successful treatment of chronic fatigue syndrome. Prior to enrollment in the Plan's Part D program, the Appellant determined that Nexavir was listed on the Plan's Drug Plan as covered Tiered 4 Drug. In 2013, Nexavir was Tier 3 drug. In 2014, it was again listed as a covered Tier 4 drug.

After enrollment in the Plan's Part D program, the Appellant submitted a prescription to her pharmacy for Nexavir, which was denied. On appeal of the denial, the Plan affirmed the denial of coverage on the basis that Nexavir vials are one of the drugs that are not a covered Part D drug or excluded from Medicare coverage by law. (Exh. 3). Upon Redetermination, the denial of coverage was affirmed on the basis that the National Drug Code (NDC) for the drug indicated that it was not an FDA approved drug product, and therefore, did not meet the definition of a Part D drug. (Exh. 5).

Section 1860 D-2(e) of the Act provides for prescription drug coverage under Medicare Part-D if the drug is used for a medically accepted indication. Section 1927(k)(6) of the Act defines the term "medically accepted indication" as any prescription drug use which is supported by one or more citations included or approved for inclusion in any of the following compendia: the

American Hospital Formulary Service Drug Information ("AHFS-DI"), the United States Pharmacopeia-Drug Information ("USP-DI"), and the DRUGDEX Information System. (Section 1927 (g)(1)(B)(i) of the Act).

The Appellant and her physician, through testimony and written documentation, support the use of the drug and its beneficial effects. The record established that Nexavir is bioidentical to Kutapressin, and has been used to treat a variety of conditions for almost 70 years, and is widely regarded as safe. The Appellant tried other medications which were not effective. Her physician prescribed Nexavir, with dramatic results. In addition, the Appellant testified that the drug is essential to her health and quality of life. The record established that the Appellant clearly relied on the Plan's representation, in its materials, that the drug was covered. On that basis, she enrolled in the Plan, and reasonably expected the Plan to keep its end of the written contract.

The Plan has denied the drug on the basis that under Medicare laws, it is not an FDA approved drug, nor is it being used for a recognized use under one of the Drug Compendia as an off-label use. A New York District Court held recently, in a 2011 case, that the definition of "covered part D drug" was not limited by whether usage is supported by approved compendia because the "includes" clause is illustrative rather than definitional. [3] Under *Layzer*, Medicare could be required to cover uses of drugs that are both off-label and "off compendia." While not precedential, the ALJ takes note of this holding.

The ALJ disagrees with Maximus' decision and the Plan's position, based on the evidence in the record. While the Plan has the option of declining to provide coverage for a drug which is not FDA approved, it also has the option of providing enhanced benefits to its enrollees which are not normally covered by Medicare. In this case, the Appellant relied on materials published by the Plan, that Nexavir was a covered, Tiered drug benefit . For the Plan to now argue that it is non-covered because it is not FDA approved is disingenuous. As stated so eloquently in Layzer v. Leavitt:

> More compelling statutory construction arguments confirm that Congress did not intend to impose a compendium requirement. In general, remedial legislation should be broadly construed. *See Henrietta D. v. Bloomberg, 331 F.3d 261, 279 (2d Cir. 2003).* In particular, the Second Circuit has said that the Social Security Act should be "liberally construed in favor of beneficiaries." *Hurley v. Bowen, 857 F.2d 907, 912 (2d Cir. 1988).* The "intent" of the Act "is inclusion rather than exclusion," *Vargas v. Sullivan, 898 F.2d 193, 196 (2d Cir. 1990),* and a more inclusive definition is consistent with these exhortations.
>
> Additionally, the Definition "should be interpreted to avoid untenable distinctions and unreasonable results whenever possible." *Amer. Tobacco Co. v. Patterson, 45 U.S. 63, 71(1982); United States v. Dauray, 215 F.3d 257, 264 (2d Cir. 2000).* The Secretary's interpretation would create arbitrarily fine and unreasonable distinctions between uses that are covered in the compendia and those that are not. [4]

[3] *Layzer v. Leavitt*, 77 F. Supp. 2d 579, 584-87 (S.D.N.Y. 2011).
[4] *Id.* .

Here, the record has established by a preponderance of the evidence that the requested drug is medically reasonable and necessary for the treatment of the enrollee's condition, after she attempted treatments with other medically accepted recommendations. All of the covered Part-D drugs and treatments of the plan's formulary for treatment of the same condition would not be as effective for the enrollee as Nexavir. To limit coverage for the Appellant based on a narrowly-interpreted use of this drug, as defined in either the FDA's approved use, or, in the Drug compendia's stated uses, would severely and arbitrarily exclude this Appellant from a substance which has a known, beneficial effect for her.

The intent of the Act is inclusion, instead of exclusion. Under the overarching reasoning of Section 1862 (a)(1)(A) of the Act, Nexavir is medically reasonable and necessary for the Appellant in treatment of her chronic fatigue syndrome, as discussed above, notwithstanding that her diagnoses does not fall squarely with those listed on any recognized Drug Compendium, or, that Nexavir is not an FDA approved drug. The Plan must provide coverage, for the year 2014, on the basis that coverage was an enhanced, supplemental benefit to the Plan's enrollees.

Therefore, the ALJ finds that the Plan is required to provide coverage for the drug Nexavir, for the Appellant under the overarching principles of Section 1862(a)(1)(A) of the Act. In addition, the Plan is obligated to reimburse the Appellant for the cost of the Nexavir drugs, purchased by her, during the period of her coverage in 2014. .

Conclusion of Law

(1) Nexavir is medically reasonable and necessary for Appellant's medical condition under Section 1862(a)(1)(A) in its successful treatment of the Appellant's chronic fatigue syndrome.
(2) Medicare is inclusional, not exclusional. *Layzer v. Leavitt, supra.*
(3) The Plan represented to the Public that Nexavir was a covered drug benefit.
(4) The Plan is required to reimburse the Appellant for her prior expenditures for the Nexavir , during the period of her coverage in 2014. This information regarding the Appellant's prior expenditures shall be obtained by the Plan from the Appellant for this purpose.

Order

The Appeal is Fully Favorable to the Appellant and the prior QIC's Decision is reversed. The Plan is required to cover Nexavir for 2014 for the Appellant 's medical condition, as part of its enhanced benefit to its enrollees. The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

MAR 2 7 2015
Date

James M. Takos
U.S. Administrative Law Judge