DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-13-2566

In the case of	**Claim for**
C.D. (Appellant)	Prescription Drug Benefits (Part D)
**** (Beneficiary)	**** (HIC Number)
United HealthCare Insurance Co./AARP MedicareRx Preferred (Part D Sponsor/Part D Plan)	**** (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 6, 2013, because there is an error of law material to the outcome of the claim and because the decision is not supported by the preponderance of the evidence in the record. *See* 42 C.F.R. § 423.2110. The ALJ directed the Medicare Part D Plan (PDP or Plan) to cover and pay for the product Theraproxen, which is described in the record as a convenience kit containing the generic nonsteroidal anti-inflammatory drug (NSAID) naproxen and the medical food Theramine. *See* Exhibit (Exh.) 22, at 1.

The Centers for Medicare & Medicaid Services (CMS), through Maximus Federal Services, the Part D independent review entity (IRE), asked the Council to take own motion review of this case in a memorandum dated July 2, 2013. The Council admits the referral memorandum into the administrative record as Exh. MAC-1. The enrollee's appointed representative, Dr. L.G.,[1] filed a response dated July 10, 2013, which includes a 7-page brief.

[1] Dr. L.G. is a Doctor of Podiatric Medicine who is employed by ****, a business affiliate of the manufacturer of Theramine. Hearing CD; *see also* Exh. MAC-1, at 10 n.13. In this action, the Council refers to the enrollee, as represented by Dr. L.G., as the "appellant."

The Council admits the appellant's response into the record as Exh. MAC-2.

The Council has carefully considered the record that was before the ALJ, as well as the referral memorandum and the appellant's response. As explained more fully below, the Council reverses the ALJ's decision. The plan is not required to cover or pay for Theraproxen for the enrollee.

DISCUSSION

The enrollee's physician asked the PDP to pre-authorize coverage of Theraproxen for the enrollee.[2] *See, e.g.,* Exh. 14, at 2.[3] The enrollee is diagnosed with radial styloid tenosynovitis and cervicalgia. *Id.* The Plan denied the request initially and on redetermination. Exh. 14 at 1; Exh. 15. The appellant requested reconsideration. Exh. 16. The IRE affirmed the coverage denial on reconsideration. Exh. 21. The appellant requested an ALJ hearing. Exh. 22. The ALJ conducted a hearing, by telephone, on January 11, 2013, at which he received testimony and argument from Dr. L.G. and Dr. D.S. on behalf of the appellant; a representative of the PDP also appeared at the hearing. Dec. at 1. The IRE participated before the ALJ by submitting a position paper. Exh. 26.

On May 6, 2013, the ALJ issued a favorable decision. In reversing the plan's and the IRE's denial of coverage for Theraproxen, the ALJ explained that he found persuasive the appellant's testimony and argument, as presented at the hearing and in written submissions. Dec. at 9. The ALJ reasoned that Theraproxen meets the statutory requirements for a Part D covered drug. *Id.* The ALJ accepted the appellant's argument that Theramine does not require approval by the Food and Drug Administration (FDA) because it is a "pre-1962 grandfathered drug eligible for exemption status under FDA rules." *Id.* The ALJ found that Theramine is "identical, similar, or related to a prior-1962 drug called Lofenalac" based on the fact that both Theramine and Lofenalac provide amino acids to patients with "amino acid deficiency disease." *Id.* at 10, 11. The ALJ also

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[2] No prescription is in the record, nor is there any medical documentation describing the enrollee's diagnoses or symptoms. The background facts are drawn from the "Case Summary" prepared by the PDP.

[3] The ALJ numbered exhibits in the record, but did not paginate the exhibits. The Council cites to page numbers within exhibits when the document cited contains internal page numbers. Where documents in the record do not include internal page numbers, the Council cites to the exhibit as a whole.

concluded that the appellant demonstrated that there was a "compelling medical need for Theraproxen to treat the enrollee's osteoarthritis of the neck. *Id.* at 11.

I. The ALJ Erred in Determining that Theraproxen Meets Part D Coverage Requirements.

Section 1860D-2(e)(1) of the Social Security Act (Act) describes a "covered part D drug" provided under the Medicare prescription drug benefit as "a drug that may be dispensed only upon a prescription" that is listed in section 1927(k)(2) of the Act at subparagraphs (A)(i) through (A)(iii) or certain biological products, insulin, and medical supplies associated with the injection of insulin.

The regulations at 42 C.F.R. § 423.100 define "Part D drug" as -

> (1) unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act) -
>
> (i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;
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> (ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;
>
> (iii) Insulin described in section 1927(k)(2)(C) of the Act;
>
> (iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or
>
> (v) A vaccine licensed under section 351 of the Public Health Service Act.

See also id., definition of "covered Part D drug."

In turn, sections 1927(k)(2)(A)(i) through (iii) of the Act refer to a drug:

> (i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;
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> (ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or
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> (iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling

As pertinent herein, in order to be covered under Part D under the above statute and implementing regulations, a drug must be approved by the FDA as described in section 1927(k)(2)(A)(i), which means that it is a drug marketed pursuant to a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA). Or the drug must be exempt from FDA approval under section 1927(k)(2)(A)(ii) as a grandfathered drug.

Theraproxen is sold as a convenience pack which includes a bottle of naproxen and a bottle of Theramine. Although naproxen is an FDA–approved drug, the appellant does not seriously contend that the Theraproxen kit, as a whole, is an approved drug. As the IRE points out, while the combination product Theraproxen has its own National Drug Code (NDC), there is no evidence of an application number for an approved NDA or ANDA for safety and efficacy; the status is "Unapproved Drug Other." Exh. MAC-1, at 5-7, *citing* FDA's Online Label Repository; Exh. 26 (attached printout of FDA Label Search). The Council has considered the materials on the FDA's website to determine whether they indicate any change in Theraproxen's status that would tend to support the enrollee representative's multiple arguments concerning Theraproxen's FDA status and the NDC registration (which the IRE recounts in detail in Exh. MAC-1, at 5-7), but we are unable to find any. *See, e.g.,* http://labels.fda.gov/getProprietaryName.cfm (last visited September 20, 2013). Additionally, as the IRE points out, the FDA's website materials state that the assignment of an NDC number does not denote FDA approval of the product in question, or that the product is a "drug," or that it is a product eligible for reimbursement by Medicare, Medicaid or other payers. *Id.* at 6 n.5.

However, the appellant asserts that Theraproxen is identical, similar, or related (within the meaning of 21 C.F.R. section 310.6(b)(1)) to a drug which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962. Exh. MAC-2, at 3-4. More specifically, the appellant contends that Theramine is identical, similar, or related to Lofenalac which was approved prior to 1962 as a drug, but which has since been reclassified by the FDA as a medical food.

A. The Record Does not Support a Finding That Theramine Is a Pre-1962 Grandfathered Drug.

Citing the manufacturer's own product information, the IRE points out that the manufacturer sells and markets Theramine as a "medical food," and that the manufacturer indicates that it is "regulated" as a "medical food." Exh. MAC-1, at 9-10. The labeling information for Theraproxen-90 states that Theramine's ingredients are a proprietary blend that includes, among other components, neurotransmitters, neurotransmitter precursors, cinnamon, grape seed extract, peptides, and flavonoids. Exh. 27, attached "Product Monograph" at 13. As the IRE argues,

while "medical foods" may be "generally recognized as safe" (GRAS), they are not themselves eligible for coverage under Medicare Part D because they are not drugs that are approved under the FDA's NDA or ANDA processes. Exh. MAC-1, at 10.[4] The appellant responds that Theramine is both a medical food and a drug. Moreover, the ALJ found that it was a grandfathered drug. We thus consider whether Theramine qualifies as a grandfathered drug.

As the IRE points out, in concluding that Theramine is a pre-1962 grandfathered drug the ALJ relied on the statements and representations of the enrollee's representative (Dr. L.G.) and Dr. D.S., who is the Chief Executive Officer of Targeted Medical Pharma, Inc. and the Chief Scientific Officer of Physician Therapeutics, LLC. Exh. MAC-1, at 10, n.13. The IRE points out that these companies manufacture Theraproxen, while the latter company is a division of Targeted Medical Pharma. *Id.* n.13. Dr. G., as noted above, is a podiatrist who is affiliated with Complete Claims Processing, Inc., which is a company that is a part of the corporate structure of Targeted Medical Pharma. *Id.*

The FDA has not approved Theramine, or Theraproxen for safety and effectiveness. In general, manufacturers of drugs that lack required approval, including those that are not marketed in accordance with an OTC drug monograph, have not provided FDA with evidence demonstrating that their products are safe and effective. FDA Compliance Policy Guide (CPG) § 440.100, Appendix, contains the following statement of FDA policy:

> Under the 1962 grandfather clause, the FD&C Act exempts a drug from the effectiveness requirements if its composition and labeling has not changed since 1962 and if, on the day before the 1962 Amendments became effective, it was (a) used or sold commercially in the United States, (b) not a new drug as defined by the FD&C Act at that time, and (c) not covered by an effective application. See Public Law 87-781, section 107 (reprinted following 21 U.S.C.A. 321); see also *USV Pharmaceutical Corp. v. Weinberger,* 412 U.S. 655, 662-66 (1973).
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> The two grandfather clauses in the FD&C Act have been construed very narrowly by the courts. FDA believes

[4] The IRE also notes, more precisely, that even if Theramine components are generally recognized as safe (GRAS) as dietary supplements, that does not mean that the product itself is a GRAS drug. Exh. MAC-1, at 10, n.12.

that there are very few drugs on the market that are actually entitled to grandfather status because the drugs currently on the market likely differ from the previous versions in some respect, such as formulation, dosage or strength, dosage form, route of administration, indications, or intended patient population. If a firm claims that its product is grandfathered, it is that firm's burden to prove that assertion. See 21 CFR 314.200(e)(5); see also *United States v. An Article of Drug (Bentex Ulcerine),* 469 F.2d 875, 878 (5th Cir. 1972); *United States v. Articles of Drug Consisting of the Following: 5,906 Boxes,* 745 F.2d 105, 113 (1st Cir 1984).

Finally, a product would not be considered a new drug if it is generally recognized as safe and effective (GRAS/GRAE) and has been used to a material extent and for a material time. See 21 U.S.C. 321(p)(1) and (2). As with the grandfather clauses, this has been construed very narrowly by the courts. See, e.g., *Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973); *United States v. 50 Boxes More or Less Etc.,* 909 F.2d 24, 27-28 (1st Cir. 1990); *United States v. 225 Cartons . . . Fiorinal,* 871 F.2d 409 (3rd Cir. 1989). See also Letter from Dennis E. Baker, Associate Commissioner for Regulatory Affairs, FDA, to Gary D. Dolch, Melvin Spigelman, and Jeffrey A. Staffa, Knoll Pharmaceutical Co. (April 26, 2001) (on file in FDA Docket No. 97N-0314/CP2) (finding that Synthroid, a levothyroxine sodium product, was not GRAS/GRAE).

As mentioned above, the Agency believes it is not likely that any currently marketed prescription drug product is grandfathered or is otherwise not a *new drug*. However, the Agency recognizes that it is at least theoretically possible. No part of this guidance, including the Appendix, is a finding as to the legal status of any particular drug product. In light of the strict standards governing exceptions to the approval process, it would be prudent for firms marketing unapproved products to carefully assess whether their products meet these standards.

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm (emphasis added) (last visited September 20, 2013).

The FDA has published the applicable standards for determining whether a drug is identical, related or similar. The regulation at 21 C.F.R. § 310.6 provides that an identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties. In general, a contention that a drug product is exempt from FDA-approval as a grandfathered drug is required to be supported by evidence of past and present quantitative formulas, labeling, and evidence of marketing. 21 C.F.R. § 314.200(e)(2). This evidence should include:

> I. Formulation.
> A. A copy of each pertinent document or record to establish the exact quantitative formulation of the drug (both active and inactive ingredients) on the date of initial marketing of the drug.
> B. A statement whether such formulation has at any subsequent time been changed in any manner. If any such change has been made, the exact date, nature, and rationale for each change in formulation, including any deletion or change in the concentration of any active ingredient and/or inactive ingredient, should be stated, together with a copy of each pertinent document or record to establish the date and nature of each such change, including, but not limited to, the formula which resulted from each such change. If no such change has been made, a copy of representative documents or records showing the formula at representative points in time should be submitted to support the statement.
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> II. Labeling.
> A. A copy of each pertinent document or record to establish the identity of each item of written, printed, or graphic matter used as labeling on the date the drug was initially marketed.
> B. A statement whether such labeling has at any subsequent time been discontinued or changed in any manner. If such discontinuance or change has been made, the exact date, nature, and rationale for each discontinuance or change and a copy of each pertinent

> document or record to establish each such discontinuance or change should be submitted, including, but not limited to, the labeling which resulted from each such discontinuance or change. If no such discontinuance or change has been made, a copy of representative documents or records showing labeling at representative points in time should be submitted to support the statement.

The IRE convincingly counters Dr. G.'s argument, which the ALJ apparently found persuasive, that Theramine is similar and related to the drug Lofenalac, which was on the market in 1962 for the treatment of amino acid deficiency diseases. Exh. MAC-1, at 10-12. The IRE points out that Dr. G.'s statement is "erroneous" because Lofenalac is an infant formula containing a decreased amount of phenylalanine for infants and children with phenylketonuria, or PKU. *Id.* at 11. While the website for the manufacturer of Lofenalac (Mead Johnson) does indicate that Lofenalac was marketed between 1950 and 1959, and was originally regulated by the FDA as a drug, in 1972, the FDA determined that this type of drug should be regulated as a "food for special dietary use." *Id.* Therefore, the IRE notes, Lofenalac is no longer marketed or regulated as a "drug." *Id.* Dr. G.'s position that Theramine is grandfathered as identical, related or similar to a pre-1962 drug is not accurate because the FDA has since determined that Lofenalac is not a drug. *Id.*, *citing* 61 Fed. Reg. 231 (Nov. 29, 1996).

The IRE also correctly states that the record contains none of the materials that the FDA requires to make a determination on grandfathered status. *Id.* at 10-12, *quoting* 21 C.F.R. § 314.200(e)(2). The Council is unable to find in the record any evidentiary foundation for the assertion that Theramine is actually identical, related or similar to Lofenalac, or, that Theramine's manufacturer has sought and obtained the FDA's grandfather exemption status.[5] The appellant's simple assertions of equivalence are not supported by the necessary level of factual detail required. *See, e.g.* Exh. MAC-2, at 3-4.

[5] Ostensibly, there would be no need to label Theramine as a "medical food" if it actually has grandfather or exempt status, but its labeling and marketing information reflects that Theramine is a prescription medical food. Exh. MAC-1, at 9.

B. The ALJ Did Not Have Authority to Determine Grandfather Exemption Status under the FDA's Regulatory Scheme.

The IRE maintains that the ALJ erred in deciding that Theramine has grandfathered exemption status, as the ALJ lacks authority to make such a determination. Exh. MAC-1, at 9. The Commissioner of Food and Drugs is responsible for making an administrative determination on a contention of exemption from the FDA's new drug approval requirements, as set forth in 21 C.F.R. § 314.200(e). *Id.* at 13. And it is the manufacturer that must seek an FDA exemption based on grandfather status. *Id.* The ALJ did not have the authority to intrude into matters reserved for the FDA. However, absent a final enforcement action by the FDA, CMS has clarified in the August 21, 2012, memorandum discussed more fully below, that for Medicare purposes an adjudicator (or CMS) may independently review whether a drug meets the criteria in section 1927(k) of the Act.

C. Theraproxen Does Not Meet the Definition of a Part D Drug on the Basis That It Contains a Part D Component.

The enrollee has argued below, and continues asserting, that Theraproxen is eligible for Part D coverage because it includes a Part D covered component. *See* Exh. 27, at 6 ("Theraproxen contains the generic naproxen which is FDA approved."); Exh. MAC-2, at 6 ("if Theramine is not a Part D covered drug, the co-administration of naproxen, a Part D covered drug, with Theramine, would make it eligible for coverage since it includes one covered Part D component"). On this point, the enrollee seems to argue that the Medicare Prescription Drug Benefit Manual (PDBM)(Pub. 100-18), Chapter 6, Section 10.3 allows for coverage of Theraproxen-90.[6] Section 10.3 provides as follows:

> **10.3 - Commercially Available Combination Products (Rev. 2; Issued: 07-18-08; Effective/Implementation Date: 07-18-08)**
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> Commercially available combination prescription drug products that contain at least one Part D drug component are Part D drugs when used for a "medically-accepted" indication, unless CMS makes the

[6] The ALJ's decision does not indicate that the ALJ expressly based his decision to direct the plan to cover Theraproxen on this point or on this PDBM section. But the IRE raises the issue, and the enrollee's exceptions to the referral may be read to include a response to it. Exhs. MAC-1 at 12-14; MAC-2, at 6. We therefore address the issue herein.

> determination that such product, as a whole, belongs in one of the categories of drugs excluded from coverage under Part D. If CMS has not provided guidance to exclude a specific combination product, such combination product, so long as it contains at least one Part D drug component, should be considered a Part D drug (unless it is excluded from coverage under Part D for another reason).

PDBM, Ch. 6, § 10.3.[7]

The appellant's arguments wholly ignore the August 21, 2012, memorandum discussed below. In that memorandum, CMS "provided guidance to exclude" a similar combination product, Theraproxen-90, on the basis that it is not a Part D covered drug. The appellant offers no argument that deference is not due this memorandum, or that the memorandum does not apply. See 42 C.F.R. § 423.2062 and Part III *infra*.

In addition, the IRE directs the Council's attention to two Council decisions regarding Theraproxen and another product (ibuprofen and Theramine), which, according to the IRE, find in relevant part that "combination drug/medical food products" do not meet the definition of a Part D drug. Exh. MAC-1, at 17. Although administrative decisions are not strictly precedential, the appellant has not argued that these prior decisions are distinguishable or inapplicable.

The Council notes the PDBM makes coverage available for "commercially available combination products" except when "excluded from coverage under Part D for another reason." PDBM, Ch. 6, § 10.3. The parenthetical language in the PDBM thus indicates that, if the product is excluded from Part D coverage for another reason, then the guidance may not apply or be relied upon to direct coverage. In other words, if a combination prescription drug product is excluded from coverage for another

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[7] The IRE states that there is no dispute as to whether or not Theraproxen-90 is being used for a medically accepted indication. Exh. MAC-1, at 3, n.2. In a prior action (M-12-680), cited by the appellant in a post-hearing brief, the Council left open the question of whether a Theramine-Naproxen combination (Theraproxen-90) fell within the coverage provisions available for "commercially available combination products" in the PDBM, Ch. 6, § 10.3. *See* Exh. 27, at 8 (the appellant's statement that the Council "upheld" the ALJ's decision is inaccurate, however, as the Council in that case declined to accept own-motion review of the ALJ's decision). Further, in subsequent cases we have found no basis to conclude that Theraproxen-90 fell within the provisions of PDBM, Ch. 6, § 10.3. *See, e.g.,* decisions in M-12-1301 and M-12-1723 (attached to Exh. MAC-1).

reason, then the fact that it contains one Part D component does not make the entire product eligible for coverage. The Theraproxen-90 convenience pack itself has a National Drug Code (NDC) identifier, but there is no approved NDA or ANDA for Theraproxen-90, which means that the product as a whole does not have FDA approval. The Council has determined herein that Theraproxen-90 is excluded from coverage under Part D on bases other than the PDBM provision. The Council thus finds no basis for covering Theraproxen as a commercially available combination product.

II. The ALJ Improperly Granted a Formulary Exception.

The ALJ's decision does not expressly state that an off-formulary exception for Theraproxen is granted. Nevertheless, the ALJ directed the plan to cover Theraproxen, which is not on the PDP's formulary. Dec. at 11. In so doing, the ALJ stated that the appellant had shown a "compelling medical need" for Theraproxen to treat the enrollee's osteoarthritis of the neck. *Id.* The Council therefore infers that the ALJ ordered that a formulary exception be made.

As the IRE points out, medical support is required to allow a formulary exception to set aside prior authorization rules for an on-formulary drug or to obtain coverage for a non-formulary drug. Exh. MAC-1, at 17. A Part D-eligible individual may appeal a decision to deny coverage for a covered Part D drug that is off-formulary only if the prescriber determines that all covered Part D drugs on any tier of the formulary for the treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects, or both.[8] *Id., citing* section 1860D-4(h)(2) of the Act. The formulary exceptions process includes the application of cost utilization tools. *Id., citing* 42 C.F.R. § 423.578(b).

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[8] As noted above, the record contains no medical evidence regarding the enrollee's condition. The enrollee's physician did not testify at the hearing. There is no indication that Dr. S., who did testify at the hearing, ever treated the enrollee. While Dr. S. testified that NSAIDs, in general, have potential adverse effects for elderly patients, there is no evidence in the record that the enrollee's prescriber determined that "all covered Part D drugs on any tier of the formulary for the treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects, or both," as required by statute. Nor do the appellant's citations to general statistics regarding the safety of Theraproxen when compared to NSAIDs satisfy this requirement. *See* Exh. MAC-2, at 6.

The exceptions process is a means of covering medically necessary drugs that are off-formulary or otherwise are restricted by utilization rules, but that means or process is limited to drugs that meet the legal definition of a Part D drug. As the IRE notes, accurately, 42 C.F.R. section 423.578 limits the employment of the exceptions process to those drugs that meet the legal definition, as the regulation states: "Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug." Exh. MAC-1 at 18, *quoting* 42 C.F.R. § 423.578(e). Because Theraproxen is not demonstrated to have FDA approval, it is not eligible for coverage as a Part D drug. Accordingly, the exceptions process may not be invoked to direct a Part D plan to cover or pay for it. The appellant's arguments for medical necessity are unavailing, as is the argument that the "insurance contract is to be construed broadly" to allow for coverage unless a "benefit is specifically excluded." *See* Exh. MAC-2, at 6.

III. Theraproxen is Not Covered per CMS Policy

With its position paper before the ALJ, the IRE submitted correspondence and a coverage memorandum issued by the Director of the CMS Medicare Drug Benefit and C & D Analysis Group (Drug Director). *See* Exh. 26 (attachment). The correspondence, dated August 21, 2012, is addressed to Medicare Part D sponsors and concerns the Part D status of Theraproxen-90. *Id.* The correspondence encloses a memorandum dated July 6, 2012, from the Drug Director to the Director of the Medicare Enrollment and Appeals Group, which "makes clear CMS' view that Theraproxen-90™ is not a Part D drug." *Id.* The Drug Director states that she is "sharing this information with you because you inquired or we are aware that recent administrative law judge (ALJ) decisions involving enrollees in your plan(s) . . . have found Theraproxen-90™ to meet the definition of a Part D drug." *Id.* The Drug Director explains that, while the policy statement does not change the individual ALJ decisions, it is CMS's position that "Theraproxen-90™, and similar unapproved products, are not Part D. drugs." *Id.*

The accompanying memorandum, dated July 6, 2012, begins by stating that its purpose "is to explain why Theraproxen-90™ does not meet the definition of a Part D drug and, therefore, cannot be covered under Medicare Part D." *Id.* at 2. CMS states that

Theraproxen-90 is a "convenience pack" of both "medical food & drug" consisting of 90 Theramine capsules and 60 Naproxen 250 mg tablets. *Id.* CMS points out that the convenience pack is marketed under a national drug code (NDC), but the convenience pack "as a whole is not approved for safety and effectiveness by the FDA." *Id.* The memorandum examines the definition of a Part D drug, as set forth in 42 C.F.R. § 423.100 and section 1927(k)(2)(A) of the Act, and concludes that Theraproxen-90 cannot be considered to be a Part D drug since "it fails to meet any of these above three prongs of the definition of [a] Part D drug." *Id.* at 3.

CMS also stated that its conclusion that Theraproxen-90 does not meet the definition of a Part D drug, and is thus not covered by Medicare, is consistent with "an FDA warning letter issued to [the manufacturer of Theraproxen-90™] on April 8, 2010, that involved convenience packs similar to Theraproxen-90™." *Id.* at 4. According to CMS, the FDA advised the manufacturer that convenience packs consisting of medical food and drugs are considered to be drugs under the Federal Food, Drug, and Cosmetic Act and thus require FDA approval for safety and effectiveness before marketing. *Id. citing http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm208680.htm.* As noted above, Theraproxen-90 has not been approved by the FDA for safety and effectiveness.

CMS further stated that Theraproxen-90 did not meet coverage requirements for "combination products." *Id. citing* MPDM Ch. 6, § 10.3. CMS concluded that Theramine alone did not independently meet the definition of a Part D drug, in part because it "is regulated as a medical food, and thus [is] not a 'drug' for purposes of § 1860D-2(e)(1)(A)" and because Theramine, "containing a proprietary blend of amino acids and other ingredients, was first manufactured after 1962 and is not identical, related or similar to any other products that fit within § 1927(k)(2)(A) (ii) or (iii)." *Id.* CMS specifically found that comparing Theramine to the infant powder formula Lofenalac for the "grandfather" exemption from FDA approval "is inappropriate because the FDA specifically removed Lofenalac™ from the drug category in 1972 to be regulated as a Food for Special Dietary Use (37 FR 18229)." *Id.* n.2. CMS summarized that "[i]n light of the foregoing, it is our view [that] Theraproxen-90™ is not a Part D drug, and therefore, it may not be covered under Part D." *Id.*

The appellant has not raised any exceptions specific to this memorandum. The Council finds that CMS's determinations that Theraproxen-90 does not meet the definition of a Part D drug, and that Theramine is not eligible for the grandfather exception for pre-1962 drugs, as set forth in the August 21, 2012, correspondence to Plan sponsors and the accompanying memorandum, dated July 6, 2012, are entitled to deference.

DECISION

It is the decision of the Medicare Appeals Council that Theraproxen lacks FDA approval, and does not otherwise meet the definition of a covered Part D drug. The plan, therefore, is not required to cover or pay for it. The ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL

/s/ Stanley I. Osborne, Jr.
Administrative Appeals Judge

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

Date: September 30, 2013