

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

**DECISION OF MEDICARE APPEALS COUNCIL**

**In the case of**

**Claim for**

S.A.B.

Prescription Drug Benefits  
(Part D)

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(Appellant)

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(Enrollee)

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(HIC Number)

AARP Medicare Rx Plan  
(by United Healthcare)

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(Part D Plan)

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(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated September 1, 2009. The ALJ found that the Part D plan is not required to cover the drug CellCept (brand name for mycophenolate mofetil) for treatment of the beneficiary's multiple autoimmune disorders, including severe relapsing polychondritis. The appellant/enrollee has asked the Medicare Appeals Council (Council) to review this decision. For the reasons stated below, the Council affirms the ALJ decision that the Part D plan is not required to cover the drug for the beneficiary under the medical circumstances presented here, but modifies the decision to supplement the rationale.

The regulation at 42 C.F.R. § 423.620 provides that an enrollee who is dissatisfied with an ALJ hearing decision concerning Part D benefits may request that the Council review the decision. The regulation further provides that the regulations codified at 42 C.F.R. part 422, subpart M regarding Council review apply to "matters addressed by [subpart D] to the extent applicable." The regulation codified at 42 C.F.R. § 422.608, which governs Council review of ALJ decisions concerning managed care benefits provided under Medicare Part C, states that the regulations in 42 C.F.R. Part 405 regarding Council review "apply to matters addressed by this subpart to the extent that

they are appropriate." Pending further clarification of the above regulations, the Council has determined that it is "appropriate" to apply the standards for Council review found at 42 C.F.R. § 405.1108(a), which provide that when a party requests that the Council review an ALJ'S decision, the Council will review the decision *de novo*.

The Council has considered the record and the request for review. The enrollee contends that the Part D plan should cover the drug CellCept for treatment of her severe relapsing polychondritis, which was first diagnosed in 2003.<sup>1</sup> She alleges that two of her treating physicians, both renowned in their respective fields, have stated that the drug is controlling the beneficiary's symptoms, that it is medically necessary for her condition, and that there would be life-threatening consequences if the medication was stopped. The beneficiary alleges that she has not had a major attack of her condition since starting the drug in 2007, and that the drug Methotrexate, which she took from 2003 through 2007, did not control the symptoms and led to Methotrexate-induced pulmonary fibrosis. The enrollee's assertions are fully supported by the medical records from her treating physicians, including Dr. Trentham (rheumatology) and Dr. Foster (ophthalmology) at Beth Israel Deaconess Medical Center.

The ALJ found that the Part D plan is not required to pay for the drug CellCept. After summarizing the QIC's similar decision, the ALJ denied coverage on the ground that the evidence failed to establish that the drug is FDA-approved for treatment of the beneficiary's condition or supported in any of the Medicare-approved compendia.

The record establishes that between 2003 and 2009, the beneficiary was diagnosed with multiple medical conditions, including severe relapsing polychondritis, orbital pseudotumor cerebri, lymphocytic colitis, and glaucoma. In 2007, the enrollee was also diagnosed with pulmonary fibrosis believed to have been caused by the drug Methotrexate, which the enrollee took from 2003-2007 for the relapsing polychondritis. In 2007, the beneficiary discontinued treatment with Methotrexate and

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<sup>1</sup> Relapsing polychondritis is an uncommon, chronic disorder of the cartilage that is characterized by recurrent episodes of inflammation of the cartilage of various tissues in the body. Tissues containing cartilage that can become inflamed include the ears, nose, joints, spine, and windpipe (trachea). The eyes, heart, and blood vessels, which have a biochemical makeup similar to that of cartilage, can also be affected. See, generally, [http://www.medicinenet.com/relapsing\\_polychondritis/article.htm](http://www.medicinenet.com/relapsing_polychondritis/article.htm).

started taking CellCept, a different immunosuppressive drug. The CellCept has not only controlled her symptoms of relapsing polychondritis better than the Methotrexate, but has not caused any pulmonary complications.

The Council finds no basis for finding the drug CellCept covered. Section 1860D-2 of the Social Security Act states that a Medicare Part D covered drug is a prescription drug which is prescribed for a "medically accepted indication," as defined in section 1927(k)(6) of the Act. Section 1927(k)(6) defines a "medically accepted indication" to be a use which is either (a) FDA-approved, or (b) supported by a listing in one of the specific drug compendia cited in section 1927(g)(1)(B)(i) of the Act. The drug compendia listed in section 1927(g)(1)(B)(i) are the American Hospital Formulary Service Drug Information (AHFS-DI), the U.S. Pharmacopoeia-Drug Information (USP-DI), and the DRUGDEX Information System (DRUGDEX).

The FDA labeling for CellCept is contained in the claim file. It states that CellCept is an immunosuppressant approved for the prophylaxis of organ rejection in patients receiving allogeneic, renal, cardiac, or hepatic transplants, and is to be used with cyclosporine and corticosteroids. It is not approved by the FDA for the treatment of any other condition, including the treatment of autoimmune disorders such as those with which the enrollee has been diagnosed.

CellCept is likewise not supported for use in the treatment of severe relapsing polychondritis in any of the drug compendia. The appellant has argued that the drug is approved for the treatment of inflammatory bowel disease (IBD) in the DRUGDEX compendia, and that her secondary diagnosis of lymphocytic colitis is a type of IBD. However, the Council notes that while IBD is listed briefly as a possible "clinical application" of CellCept in the DRUGDEX, the actual discussion of the drug's use in IBD summarizes the findings as follows:

FDA Approval: Adult, no; Pediatric, no.  
Efficacy: Adult, Evidence is inconclusive.  
Recommendation: Adult, Class III.  
Strength of Evidence: Adult, Category B.

A class III strength of recommendation is explained in DRUGDEX as follows: "Not Recommended. The given test, or treatment is not useful, and should be avoided." Category B in strength of evidence is "based on data derived from":

Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients often had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, ect.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).

Thus, DRUGDEX does not support the use of CellCept in treating IBD.

The AHFS-DI likewise does not list the treatment of general IBD as a possible use of CellCept, but only lists its uses to include the rejection of organs following kidney, heart or liver transplant, as well as in the management of Crohn's disease. Thus, the AHFS-DI does not support the use of CellCept in the treatment of IBD other than specifically with regard to Crohn's disease. The Council further notes that the USP-DI is no longer in publication and is no longer an available resource for up-to-date information on currently-marketed drugs.

Finally, the Council notes that the record contains a copy of an August 11, 2009 letter addressed to the enrollee from a representative in the Global Medical Information Department of Vifor Pharma. Vifor Pharma performs clinical research on finding treatment options for patients with less common diseases, such as relapsing polychondritis.<sup>2</sup> In partnership with Hoffman-LaRoche, the manufacturer of CellCept, Vifor Pharma undertook two clinical trials to study CellCept's use in autoimmune diseases. In her letter, apparently in response to an inquiry of the enrollee, the Vifor Pharma representative states:

Thank you for your enquiry to Vifor Pharma Medical Information last Friday regarding CellCept and the treatment of several autoimmune diseases (Relapsing polychondritis, Orbital pseudotumor cerebri, Lymphocytic colitis and Vitiligo.) I understand from our conversation that you are seeking evidence that CellCept is effective in the treatment of these diseases as you have a court case this Thursday to claim for reimbursement costs.

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<sup>2</sup> See, generally, the company's website at [www.viforpharma.com](http://www.viforpharma.com).

As explained to you over the telephone, the use of CellCept is not licensed in any autoimmune diseases so we cannot recommend the use of CellCept for your disease as it would be considered off-label use. However, we performed extensive searches of the literature publications available to us and, as per my email on Friday, unfortunately there seems to be very limited information available on the effectiveness of CellCept treatment in the diseases you have.

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CellCept is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants and in patients receiving allogeneic cardiac transplants. CellCept should be used concomitantly with cyclosporine and corticosteroids. We do not recommend the use of our products for any indication, claim, dosage or route of administration not covered in the product's package insert.

Thus, the record clearly establishes that the use of CellCept in treating the enrollee's autoimmune conditions is an off-label (not FDA-approved) use which is not supported by the approved drug compendia. Since it is neither FDA-approved nor supported in the compendia for treatment of any of the conditions with which the enrollee is diagnosed, it is not a covered Medicare Part D drug. For these reasons, the Council has no authority to direct the Part D plan to furnish or provide reimbursement for the drug CellCept even where, as here, the drug is medically necessary or even critical for the enrollee's treatment.

Accordingly, the Council affirms the ALJ's decision, as supplemented above.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson  
Administrative Appeals Judge

/s/ Clausen J. Krzywicki  
Administrative Appeals Judge

Date: December 11, 2009