

May 20, 2024

**Appeal Number:**

**1-14041733629**

JAMES RODENHISER

(b) (6)

RE: [REDACTED]  
\*\*\*\*\*\_pj12

Dear JAMES RODENHISER:

This letter is about our decision on your appeal to CIGNA HEALTHSPRING. You asked CIGNA HEALTHSPRING to provide reimbursement for METHOCARBAMOL.

**Your appeal decision is unfavorable**

The decision for this appeal is UNFAVORABLE based on a new independent review. This means that CIGNA HEALTHSPRING is not required to provide reimbursement for METHOCARBAMOL according to Medicare rules.

**Your right to appeal**

If you don't agree with this decision, you may have rights to a hearing with an Administrative Law Judge (ALJ). For more information on how to appeal, see "Important Information About Your Appeal Rights" included with this notice. You must file your appeal in writing, within 60 days of the day you get this letter.

**Get help and more information**

For questions about this letter, call 1-800-MEDICARE (1-800-633-4227). TeleTYpe (TTY) users call 1-877-486-2048.

**Medicare rules**

Section 1860D-2(e)(4) of the Social Security Act defines "medically-accepted indication," in part by reference to Section 1927(k)(6) of the Social Security Act, to any use of a covered Part D 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 Section 1927(g)(1)(B)(i) of the Social Security Act. The recognized compendia are: 1) American Hospital Formulary Service Drug Information, and 2) DRUGDEX® Information System.

The definition of medically accepted indication also means, in the case of a covered Part D drug used in

**Contact Information**

If you have questions, write or call:

**C2C Innovative Solutions, Inc.**  
Medicare Part D QIC  
P.O. Box 44167  
Jacksonville, FL  
32231-4167

*Telephone number:*  
1- 833-919-0198

Who we are:  
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

an anticancer chemotherapeutic regimen, the definition of medically accepted indication in Section 1861(t)(2)(B) of the Social Security Act. Thus, Part D sponsors will be required to thoroughly understand and apply Part B's definition of an anti-cancer chemotherapeutic regimen, utilize Part B compendia, and consider peer reviewed medical literature when necessary. The Centers for Medicare & Medicaid Services Internet-Only Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50.4.5 (<http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>) will be the authoritative guidance for Part D sponsors in their consideration of medically accepted indications for Part D anti-cancer chemotherapeutic claims.

Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically accepted indications using the tools and data available to them to make such determinations. Part D sponsors must reference all the Centers for Medicare & Medicaid Services recognized compendia to determine whether there are any supportive citations, prior to determining that a drug is not being used for a medically accepted indication. Part D sponsors may rely on utilization management policies and procedures, approved by the Centers for Medicare & Medicaid Services where required (see the Centers for Medicare & Medicaid Services Internet-Only Manual, Publication 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.2.1), to make such determinations. Dispensing pharmacists are not required to contact each prescriber to verify a prescription is being used for a medically accepted indication. Also, medically accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Part D sponsors may have dose limitations based on Food and Drug Administration labeling, but an enrollee may request (and be granted) an exception to a dose restriction through the formulary exception process based on medical necessity criteria.

Additionally a Part D drug must be used for a medically accepted indication that facilitates the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines). Consequently, if a drug works on medical equipment or devices and is not used for a medically accepted indication of therapeutic value on the body, it cannot satisfy the definition of a Part D drug. For example, a heparin flush is not used to treat a patient for a medically accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin's use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. Heparin would therefore not be a Part D drug when used in a heparin flush. [Sections 1860D-2(e)(4) and 1927(k)(6) of the Social Security Act; the Centers for Medicare & Medicaid Services Internet-Only Manual, Publication 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Section 10.6]

### **Explanation of decision**

At issue is coverage for Methocarbamol 500 milligram tablet to treat lumbar spondylosis. The Part D plan denied the request for coverage.

We received the case to perform an independent and de novo review. To make our decision, we reviewed all available documentation.

In order for a drug to be covered by Medicare Part D, it must be prescribed for a medically accepted indication outlined in the Medicare approved compendia. The use of the requested drug to treat the noted condition is an off-label use. The Medicare-approved compendia do not contain any citations to support the use of the requested drug, as prescribed, for the treatment of this condition. Therefore, the drug is being prescribed for a non-medically accepted indication.

A physician reviewed the appeal and determined that the requested drug is not eligible for Part D coverage.

In conclusion, the decision of the QIC is unfavorable.

Sincerely,

Dylan Deatrich, M.D.  
Medical Director

cc: CIGNA HEALTHSPRING S5617