

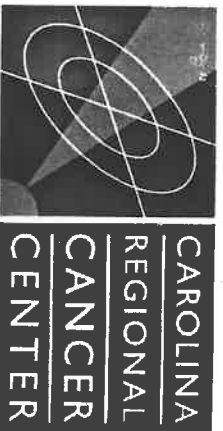
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
Bouling	1-23-07

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 000478	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>Extend until 2/12/07 per Nancy Robert. w/ 2/5/07 e-mail attached</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <u>2-1-07</u> <input type="checkbox"/> FOIA DATE DUE _____ <input type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1. <i>* E-mail from Nancy Robert dated 2/21/07</i>			
2. <i>Cancel 4-3-07, letter attached.</i>			
3.			
4.			



R. Steven Bass, MD
Todd E. Williams, MD
Paul G. Goetowski, MD
Board Certified Radiation Oncologists
Stephen F. Andrews, DO
Board Eligible Radiation Oncologist

Doc - Bardwin
W. Approp. Surg.

MUSC
HOLLINGS CANCER CENTER

RECEIVED

January 12, 2007

JAN 22 2007

Department of Health & Human Services
OFFICE OF THE DIRECTOR

Marion Burton, MD
Department of Health and Human Services
1801 Main Street
PO Box 8206
Columbia, SC 29201

Dear Doctor Burton:

RE: Quadramet for cancer patients with bone metastasis

It has recently come to my attention that Quadramet (Samarium-153) is not available for Medicaid patients with bone metastases from a cancer primary. I feel that this is a gross oversight, since this drug has been fully approved by the FDA and is covered as an injectable cancer treatment agent by Medicare nationally. It was offered to substitute Metastron (Strontium-89), which is an inappropriate substitution. Although both drugs were developed for the same purpose of treating bone metastases, they are not equivalent at all.

While Strontium-89 has a half-life of 50 days and a penetration of 2.4 mm into soft tissue, Samarium-153 has a much shorter half-life of 1.9 days and a shallower penetration of 0.55 mm. The shorter half-life creates less chronic exposure to the bone marrow underlying the bone surface and the shallower penetration reduces that bone marrow exposure even further. These two factors alone decrease the bone marrow toxicity by a factor of at least four, which reduces the complication of neutropenia and anemia dramatically. The targeted delivery directly to the surface of bone damage by the carrier molecule (lexidronam) not only restricts the Samarium delivery to the area that is most needed, it also helps to speed the elimination of unused radio-active material from the body, which further reduces the toxicity.

Not only do these improvements in delivery and radionuclide selection appear to improve the therapeutic effectiveness of Quadramet, it also allows it to be used on a repeated basis at 3-6 month intervals, if symptoms recur. Because of the increased toxicity of Strontium-89, repeated doses are rarely tolerated. Once patients develop metastatic disease, the progress is often chronic, with slowly progressive pain, disability and decreased quality of life. The newer targeted radioactive agents, such as Quadramet, provide a potential benefit for these patients not only with an initial dose, but over a much longer period of their metastatic therapy. Compared with multiple individual external radiation treatments to several sites, Quadramet provides a potential tool that not only helps multiple sites simultaneously, but probably at a lower cost of a protracted course of external radiation treatment. I feel that it is entirely inappropriate that this more selective and more effective agent is not supported for Medicaid patients, which substitutes an older and less effective treatment with higher complication and side effect profile. I respectfully request that this inappropriate decision be review and revised as soon as possible.

Sincerely,
Paul G. Goetowski
PAUL G. GOETOWSKI, MD
Carolina Regional Cancer Center

PGG:aml

From: Nancy Rabert
To: Brenda James; Margarete Keller
Date: 2/5/2007 9:42 am
Subject: Log 000478 - Mr. Assey is asking for an extension

Please extend to Monday, 2/12. The log is being re-assigned from Mr. Assey to Val.

From: Nancy Rabert
To: Brenda James; Margarete Keller
Date: 2/21/2007 8:56 am
Subject: Log 000478

CC: Susan Delaine; Valeria Williams
Valeria Williams called. This letter is late.
She is working with Dr. Burton to prepare the response.



State of South Carolina
Department of Health and Human Services

Mark Sanford
Governor

Robert M. Kerr
Director

April 3, 2007

Paul G. Goetowski, MD
Carolina Regional Cancer Center
4708 Oleander Drive
Myrtle Beach, SC 29577

Re: Quadramet®

Dear Dr. Goetowski:

Thank you for the letter requesting Medicaid's coverage of Quadramet® for patients bone metastases from a cancer primary. We have reviewed your request and agree that Quadramet® should be a covered service with a Prior Authorization (PA).

Program staff is in the process of developing the PA criteria for this drug. Once an outline is developed, a copy will be forwarded to you. We would ask that when you received the draft criteria you review the outline and provide us with your comments and recommendations.

Thank you for taking the time to contact us and for your continued support and participation in the South Carolina Medicaid program. If you have any questions or if we can be of further assistance, please contact Ms. Valeria Williams, Division for Physician Services, at (803) 898-3477.

Sincerely,

A handwritten signature in cursive script, appearing to read "Marion Burton", is written over the printed name.

O. Marion Burton, MD
Medical Director

OMB/bk