

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

**ACTION REFERRAL**

TO <i>Myers</i>	DATE <i>4-13-09</i>
--------------------	------------------------

<b>DIRECTOR'S USE ONLY</b>	<b>ACTION REQUESTED</b>
1. LOG NUMBER  <i>100573</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR:  <i>Cc: Ms. Forlmer</i> 	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____
	<input type="checkbox"/> FOIA DATE DUE _____
	<input checked="" type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

GE Healthcare

*Log. Myers  
K/A*

**RECEIVED**

APR 09 2009

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

**CONFIDENTIAL AND PROPRIETARY-- NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR  
OTHERWISE**

April 6, 2009

Ms. Emma Forkner  
Director  
Department of Health & Human Services  
P.O. Box 8206  
1801 Main Street  
Columbia, SC 29202-8206

Dear Ms. Forkner:

As a unit of General Electric Company, GE Healthcare is the manufacturer of several diagnostic radiopharmaceuticals, including Myoview (technetium Tc-99m tetrofosmin). We are devoted to medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research and drug biopharmaceutical development. We wanted to inform the State Medicaid program about Myoview's reported and published prices, its distribution, preparation of the product, its pricing, and reimbursement. We greatly appreciate the State Medicaid program's commitment to providing high quality products and services to beneficiaries of the federal health care programs. We designate this document as confidential, proprietary, and reflective of trade secrets.

We have shared the information contained in this letter with the organizations that calculate and publish average wholesaler price ("AWP") for Myoview, as well as the Centers for Medicare and Medicaid Services ("CMS"). The organizations that calculate and publish AWP are commonly referred to as pricing compendia. We have urged the pricing compendia to also consider this information as they independently calculate and establish AWPs. We have also encouraged these organizations to seek similar data from all other radiopharmaceutical manufacturers. Further, we have offered to provide similar information regarding four other radiopharmaceuticals manufactured by GE Healthcare. We ask that you use this information to set appropriate reimbursement policies for all radiopharmaceutical products.

General Electric Company  
Amersham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T F



# GE Healthcare

**CONFIDENTIAL AND PROPRIETARY – NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR OTHERWISE**

## **I. Distribution and Preparation**

Myoview, an FDA-approved reagent kit, is supplied as a kit comprised of five vials for use in the preparation of a technetium Tc99m tetrofosmin intravenous injection. Each vial contains a non-radioactive drug substance, tetrofosmin, in powder form. We distribute Myoview kits from our U.S. distribution facility to three types of customers for activation: independent pharmacies (66%), more than 30 GE-owned pharmacies (33%), and hospitals and clinics that activate Myoview on their own (1%) (3Q 2008 data).

Before Myoview can be administered to a patient, a nuclear pharmacist must activate each vial and pull off radioactive liquid doses into individual syringes. The process of activating the powder product involves substantial cost. Myoview powder is activated by the addition of technetium Tc99m solution which is extracted from a generator. After an incubation period, the nuclear pharmacist draws down individual liquid doses of activated drug based on physician orders. On average, each vial of tetrofosmin yields approximately 6 liquid doses. Specifically, available data from January 1998 through October 2008 indicates that the average number of doses per vial was 6.2.

Each physician prescription indicates a particular radioactivity level (measured in millicuries of Tc99) to be delivered at a particular time. Because Tc99 decays rapidly, the greater the lag time between preparation and injection, the higher the dose that must be prepared. Pharmacies courier activated liquid doses to providers for subsequent injection into patients for the detection of coronary artery disease.

## **II. GEHC's Pricing**

*Non-activated product (tetrofosmin powder):* The current commercial list price for Myoview kits sold from the company's manufacturing facility is \$3,033.90 per kit. This list price has not changed since 2005, and was last provided to First Databank and Red Book within the past two months. Less than 1% of the Myoview kits sold from the company's manufacturing facility (i.e., excluding those kits transferred to GE-owned pharmacies) in 3Q 2008 was sold at that commercial list price. Some customers negotiate a contracted purchase price less than list price, while other customers negotiate for a lesser price at the time of purchase. Though Myoview is generally distributed in the form of a 5-vial kit, it is generally priced on a per-dose basis. For 3Q 2008, the average price per dose sold from the company's manufacturing facility was \$33.80. At 5 vials per kit and assuming 6 doses per vial, this average price per dose corresponds to an average per kit price of \$1,014. The range of sales prices for doses sold to non GE-owned pharmacies (excluding hospitals, which occasionally purchase at list price) was \$29.00 to \$46.10 per dose. Assuming 30 doses per kit, these per dose prices correspond to a range of per kit prices from \$870 to \$1383.

General Electric Company  
Amersham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T  
F



# GE Healthcare

**CONFIDENTIAL AND PROPRIETARY – NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR OTHERWISE**

On rare occasions, GE-owned pharmacies sell kits or vials to nearby independent pharmacies, hospitals or clinics. The current commercial list price for kits sold through one of our nuclear pharmacy locations is \$3,439.80. Less than one percent of such sales were made at that pharmacy commercial list price in 3Q 2008. For 3Q 2008, the average price of kits sold from GE-owned pharmacies was \$2040.88.

*Activated product:* GE Healthcare sells radioactive liquid Myoview doses through its pharmacies. On a per dose basis, the price for these activated Myoview doses is greater than the price of the tetrofosmin powder kits to account for the Tc-99m, labor, handling, transportation, distribution, and other overhead costs, in addition to the cost of the Myoview powder. The current commercial list price per activated, liquid dose is \$140.00. Less than one percent of all activated dose sales were made at this price during 3Q 2008. For 3Q 2008, the average activated liquid dose price from GE Healthcare pharmacies was approximately \$55.80. At 5 vials per kit and assuming 6 doses per vial, this average price per liquid dose corresponds to an average per kit price of \$1,674. The range of actual sales prices for activated doses was \$26.11 to \$147.00 per dose. Assuming 30 doses per kit, these per dose prices correspond to a range of per kit prices from \$783.30 to \$4400.

### III. Reimbursement

Red Book's current published AWP value is \$3,640.68 per kit. There is no published per dose AWP for Myoview. Thus, for reimbursement purposes, the per-kit AWP is converted by CMS into an activated dose reimbursement rate. Providers seek reimbursement from payors for activated liquid Myoview doses by billing HCPCS code A9502 (Technetium Tc-99m Tetrofosmin, diagnostic, per study dose). The cost of such activated liquid doses to the provider includes not only the cost of the tetrofosmin powder but also the costs associated with the activation process, including but not limited to the radioactive technetium Tc-99m, labor, handling, and transportation. We also understand that providers incur substantial storage, handling, administration, disposal, and other costs that are uniquely associated with radiopharmaceuticals that are not separately reimbursed by payors.

\* \* \*

GE Healthcare also manufactures four other radiopharmaceutical products – Ceretec (kit for preparation of technetium Tc-99 exametazime), Indium Oxine (indium in 111 oxyquinolone), Metastron (strontium 89 chloride injection), and AdreView (lobeguanine 1123 Injection). Each of these products is distributed through a complex chain of distribution, and there are differentials between AWP and provider acquisition costs for each of them. Upon your request, we would be happy to provide comparable distribution, preparation, pricing and reimbursement information regarding these other radiopharmaceuticals.

\* \* \*

General Electric Company  
Amersham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T  
F



# GE Healthcare

**CONFIDENTIAL AND PROPRIETARY – NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR OTHERWISE**

Thank you in advance for your attention to this matter. We ask that you use this information in determining what you believe to be an appropriate reimbursement for our product and the substantial related costs. If you have any questions about the information that we have presented to you here, please let us know and we will be happy to discuss these questions with you.

Sincerely,



Terri Moench

General Electric Company  
Amersham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T  
F



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

**ACTION REFERRAL**

TO <i>Myers / Stone</i>	DATE <i>4-13-09</i>
----------------------------	------------------------

<b>DIRECTOR'S USE ONLY</b>	<b>ACTION REQUESTED</b>
1. LOG NUMBER <b>100573</b>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR: <i>Ce: Ms. Forlner</i> <i>In Margie's Hwy 7/30/09</i>	<input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____ <input type="checkbox"/> FOIA DATE DUE _____ <input checked="" type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

GE Healthcare

*Log: Myers  
K/A*

RECEIVED

APR 09 2009

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

**CONFIDENTIAL AND PROPRIETARY – NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR OTHERWISE**

April 6, 2009

Ms. Emma Forkner  
Director  
Department of Health & Human Services  
P. O. Box 8206  
1801 Main Street  
Columbia, SC 29202-8206

Dear Ms. Forkner:

As a unit of General Electric Company, GE Healthcare is the manufacturer of several diagnostic radiopharmaceuticals, including Myoview (technetium Tc-99m tetrofosmin). We are devoted to medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research and drug biopharmaceutical development. We wanted to inform the State Medicaid program about Myoview's reported and published prices, its distribution, preparation of the product, its pricing, and reimbursement. We greatly appreciate the State Medicaid program's commitment to providing high quality products and services to beneficiaries of the federal health care programs. We designate this document as confidential, proprietary, and reflective of trade secrets.

We have shared the information contained in this letter with the organizations that calculate and publish average wholesaler price ("AWP") for Myoview, as well as the Centers for Medicare and Medicaid Services ("CMS"). The organizations that calculate and publish AWP are commonly referred to as pricing compendia. We have urged the pricing compendia to also consider this information as they independently calculate and establish AWP. We have also encouraged these organizations to seek similar data from all other radiopharmaceutical manufacturers. Further, we have offered to provide similar information regarding four other radiopharmaceuticals manufactured by GE Healthcare. We ask that you use this information to set appropriate reimbursement policies for all radiopharmaceutical products.

General Electric Company  
Amersham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T F



# GE Healthcare

**CONFIDENTIAL AND PROPRIETARY – NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR OTHERWISE**

## **I. Distribution and Preparation**

Myoview, an FDA-approved reagent kit, is supplied as a kit comprised of five vials for use in the preparation of a technetium Tc99m tetrofosmin intravenous injection. Each vial contains a non-radioactive drug substance, tetrofosmin, in powder form. We distribute Myoview kits from our U.S. distribution facility to three types of customers for activation: independent pharmacies (66%), more than 30 GE-owned pharmacies (33%), and hospitals and clinics that activate Myoview on their own (1%) (3Q 2008 data).

Before Myoview can be administered to a patient, a nuclear pharmacist must activate each vial and pull off radioactive liquid doses into individual syringes. The process of activating the powder product involves substantial cost. Myoview powder is activated by the addition of technetium Tc99m solution which is extracted from a generator. After an incubation period, the nuclear pharmacist draws down individual liquid doses of activated drug based on physician orders. On average, each vial of tetrofosmin yields approximately 6 liquid doses. Specifically, available data from January 1998 through October 2008 indicates that the average number of doses per vial was 6.2.

Each physician prescription indicates a particular radioactivity level (measured in millicuries of Tc99) to be delivered at a particular time. Because Tc99 decays rapidly, the greater the lag time between preparation and injection, the higher the dose that must be prepared. Pharmacies courier activated liquid doses to providers for subsequent injection into patients for the detection of coronary artery disease.

## **II. GEHC's Pricing**

*Non-activated product (tetrofosmin powder):* The current commercial list price for Myoview kits sold from the company's manufacturing facility is \$3,033.90 per kit. This list price has not changed since 2005, and was last provided to First Databank and Red Book within the past two months. Less than 1% of the Myoview kits sold from the company's manufacturing facility (i.e., excluding those kits transferred to GE-owned pharmacies) in 3Q 2008 was sold at that commercial list price. Some customers negotiate a contracted purchase price less than list price, while other customers negotiate for a lesser price at the time of purchase. Though Myoview is generally distributed in the form of a 5-vial kit, it is generally priced on a per-dose basis. For 3Q 2008, the average price per dose sold from the company's manufacturing facility was \$33.80. At 5 vials per kit and assuming 6 doses per vial, this average price per dose corresponds to an average per kit price of \$1,014. The range of sales prices for doses sold to non GE-owned pharmacies (excluding hospitals, which occasionally purchase at list price) was \$29.00 to \$46.10 per dose. Assuming 30 doses per kit, these per dose prices correspond to a range of per kit prices from \$870 to \$1383.

General Electric Company  
Amer sham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T  
F



# GE Healthcare

**CONFIDENTIAL AND PROPRIETARY – NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR OTHERWISE**

On rare occasions, GE-owned pharmacies sell kits or vials to nearby independent pharmacies, hospitals or clinics. The current commercial list price for kits sold through one of our nuclear pharmacy locations is \$3,439.80. Less than one percent of such sales were made at that pharmacy commercial list price in 3Q 2008. For 3Q 2008, the average price of kits sold from GE-owned pharmacies was \$2040.88.

*Activated product:* GE Healthcare sells radioactive liquid Myoview doses through its pharmacies. On a per dose basis, the price for these activated Myoview doses is greater than the price of the tetrafosmin powder kits to account for the Tc-99m, labor, handling, transportation, distribution, and other overhead costs, in addition to the cost of the Myoview powder. The current commercial list price per activated, liquid dose is \$140.00. Less than one percent of all activated dose sales were made at this price during 3Q 2008. For 3Q 2008, the average activated liquid dose price from GE Healthcare pharmacies was approximately \$55.80. At 5 vials per kit and assuming 6 doses per vial, this average price per liquid dose corresponds to an average per kit price of \$1,674. The range of actual sales prices for activated doses was \$26.11 to \$147.00 per dose. Assuming 30 doses per kit, these per dose prices correspond to a range of per kit prices from \$783.30 to \$4400.

### III. Reimbursement

Red Book's current published AWP value is \$3,640.68 per kit. There is no published per dose AWP for Myoview. Thus, for reimbursement purposes, the per-kit AWP is converted by CMS into an activated dose reimbursement rate. Providers seek reimbursement from payors for activated liquid Myoview doses by billing HCPCS code A9502 (Technetium Tc-99m Tetrafosmin, diagnostic, per study dose). The cost of such activated liquid doses to the provider includes not only the cost of the tetrafosmin powder but also the costs associated with the activation process, including but not limited to the radioactive technetium Tc-99m, labor, handling, and transportation. We also understand that providers incur substantial storage, handling, administration, disposal, and other costs that are uniquely associated with radiopharmaceuticals that are not separately reimbursed by payors.

\* \* \*

GE Healthcare also manufactures four other radiopharmaceutical products – Ceretec (kit for preparation of technetium Tc-99 exametazime), Indium Oxine (indium in 111 oxyquinolone), Metastron (strontium 89 chloride injection), and AdreView (labeled guanane 123 Injection). Each of these products is distributed through a complex chain of distribution, and there are differentials between AWP and provider acquisition costs for each of them. Upon your request, we would be happy to provide comparable distribution, preparation, pricing and reimbursement information regarding these other radiopharmaceuticals.

\* \* \*

General Electric Company  
Amersham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T  
F



# GE Healthcare

**CONFIDENTIAL AND PROPRIETARY – NOT SUBJECT TO RELEASE OR PROCESS UNDER FOIA OR OTHERWISE**

Thank you in advance for your attention to this matter. We ask that you use this information in determining what you believe to be an appropriate reimbursement for our product and the substantial related costs. If you have any questions about the information that we have presented to you here, please let us know and we will be happy to discuss these questions with you.

Sincerely,



Terri Moench

General Electric Company  
Amersham plc  
101 Carnegie Center  
Princeton, NJ 08540  
U.S.A.

T  
F

