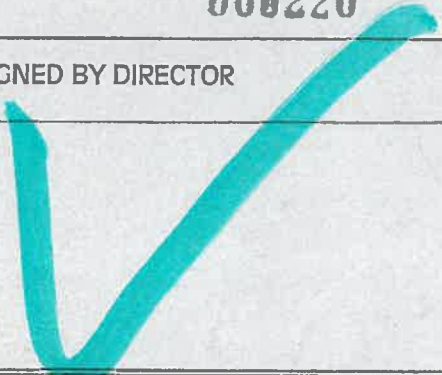


DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO <i>Jingleton</i>	DATE <i>3-31-15</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>000220</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR 	<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.			

March 23, 2015

RECEIVED

MAR 30 2015

Department of Health & Human Services
OFFICE OF THE DIRECTOR

Christian Soura
South Carolina Department of Health & Human Services
1801 Main Street, PO Box 8206
Columbia, SC 29201-8206

Re: Myoview (Kit for preparation of Technetium Tc-99m Tetrofosmin for Injection)

Dear Sir or Madam:

GE Healthcare ("GEHC"), a unit of General Electric Company, is a manufacturer of several diagnostic radiopharmaceuticals, including Myoview™ (Kit for Preparation of Technetium Tc-99m Tetrofosmin for Injection). We wish to provide you with updated information regarding Myoview's preparation and distribution as well as its reported prices, average wholesale price ("AWP"), and sales price. In April 2009, GEHC submitted a letter to your agency regarding Myoview. That letter addressed a prior 10mL preparation of the product that is no longer distributed in the United States. This letter seeks to provide you with information regarding the current 30mL preparation of Myoview⁴¹ and to explain a recent price correction made by GEHC.

Preparation and Distribution

The Myoview 30mL is supplied as a kit comprised of 5 multi-use vials for use in the preparation of a technetium Tc99m Tetrofosmin intravenous injection. Each vial contains a non-radioactive ("cold") lyophilized powder (Tetrofosmin). Before Myoview can be administered to a patient, a nuclear pharmacist must reconstitute each vial and draw doses of the radioactive Myoview into individual syringes. Myoview lyophilized powder is reconstituted by the addition of Technetium (Tc99m) radioactive solution, which is produced from a technetium generator. Each vial yields varying doses of radioactive product, depending on various factors, including the number of unit dose orders for any given timeframe within the pharmacy, the calibration time for the requested doses, and the requested unit dose size and volume for each patient. However, on average, each 30mL vial yields approximately 25 unit doses, as opposed to the approximately 6 unit doses prepared from the 10mL vial. In order to calculate the average number of unit doses per vial, GEHC takes the total number of vials prepared by the GE Healthcare nuclear pharmacies and those sold to commercial radiopharmacies that report back to GEHC the number

⁴¹ The 30mL preparation of Myoview was approved by the Food and Drug Administration ("FDA") in July 2005, but the first commercial sale of the product was not until 2Q 2009. On January 21, 2013, GEHC announced it would cease manufacturing the 10mL preparation of the product in the United States.



GE Healthcare

of unit doses prepared from a 30mL vial. The actual average may be lower or higher depending on the unit dose demand and size of the radiopharmacy.

In general, these kits are sold from GEHC's distribution facility to nuclear pharmacies, which reconstitute the lyophilized tetrofosmin with the radioactive Technetium (Tc99m) to make the product "hot." In addition to distributing kits of Myoview to nuclear pharmacies, GEHC operates a number of its own nuclear pharmacies, which, like independent nuclear pharmacies, activate the product and sell hot radioactive doses to providers. A small number of hospitals and clinics purchase the Myoview kit and activate the product on their own.

Providers generally purchase the individual doses of hot product from nuclear pharmacies for use in each applicable patient. Though Myoview is generally distributed by GEHC in the form of a 5 vial kit, it is generally sold, priced, and reimbursed to providers on a per-unit dose basis after reconstitution.

Current Pricing

As you know, AWP is a price published by various compendia, such as Red Book, Wulters-Kluwer, and First Databank. It is generally 20% greater than the manufacturer's reported listed direct price. The listed direct price, by definition, does not include any discounts or other price concessions, such as rebates, that may be negotiated with the manufacturer.

As of January 2015, the current AWP listed in Red Book, Wulters-Kluwer, and First Databank for a 5 vial kit of the 10mL preparation of Myoview was \$3,508.62 and the listed direct price was \$2,923.85. The compendia also provide the vial listed direct price as \$584.77. Assuming 6 unit doses per 10mL vial, the unit dose price would be \$97.46. Although the compendia do not provide a per unit dose price for Myoview, reimbursement is determined based on a unit dose price. These listed direct prices were associated with the prior discontinued 10mL preparation and are not adjusted for the currently available 30mL preparation.

Price Correction

Beginning on April 1, 2015, the new listed direct price in the compendia for a 5 vial kit of the 30mL preparation of Myoview is \$12,182.50, which corresponds to a vial listed direct price of \$2,436.50. Assuming 25 unit doses per vial, the unit dose price would be \$97.46, equal to the unit dose price of the prior 10mL preparation. GEHC estimates that approximately 1% of providers will purchase the product at this price, based upon historical purchases at the listed direct price. Other purchasers secure the product at lower prices, including (1) the non-market prices used to transfer product to GEHC nuclear pharmacies and (2) independent nuclear pharmacies with a discount contract in place. GEHC conducted a review of sales over the past two years and identified that the average price paid by contracted independent customers was \$41.04 per unit dose, or \$1,025 per vial and \$5,130 per kit.



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Because the price in the compendia was originally associated with the 10mL kit, GEHC plans to update the compendia to correspond to the larger, 30mL Myoview kit and to reflect the updated listed direct price to customers for a dose of Myoview, as set out above.

* * *

We are disclosing to you, in the interest of transparency, the listed direct price and the manner in which the compendia are expected, based on their procedures, to calculate an AWP for Myoview. This letter is being sent to the Centers for Medicare and Medicaid Services, all Medicare Administrative Contractors, all state Medicaid agencies, the top 100 private payors, and the compendia. We ask that you use this information in determining what you believe to be an appropriate reimbursement for our product. 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.

Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,



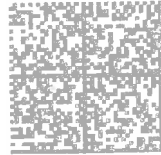
Rick Cornell
President, Medi-Physics Inc. d.b.a. GE Healthcare
GE Healthcare



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Department of Health & Human Services
OFFICE OF THE DIRECTOR

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