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[insideview]

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BRACCO BRINGS CARDIAC PET IMAGING TO MORE PROVIDERS

A conversation with **Holly Tappen**, Manager of Strategic Initiatives at Bracco Diagnostics Inc.

Cardiac PET is a powerful imaging modality for diagnosing heart disease. While many healthcare providers have PET/CT cameras, they might lack the capability to offer cardiac PET if their anticipated use is too low to warrant the investment. Bracco Diagnostics Inc. launched its Bracco Mobile Isotope Service (BMIS) program in 2021 to address this and other challenges to offering cardiac PET imaging for patients. The service provides CardioGen-82® (Rubidium Rb 82 generator) and infusion systems to U.S. healthcare facilities on an as-needed basis. Holly Tappen describes how this service reduces operating costs for hospitals and small imaging sites, increases flexibility, and expands access.

What are some obstacles to U.S. healthcare providers offering cardiac PET?
There are upfront costs, particularly if the site does not already have a PET scanner. Additionally, a full-time cardiac PET imaging program requires a commitment for a monthly generator, and it requires sufficient patient volume to recoup these costs. These challenges can sometimes make cardiac PET imaging prohibitive for smaller sites that don't have consistent patient numbers, such as those not affiliated with large institutions or in major urban areas.

How does Bracco's Mobile Isotope Service overcome these hurdles?
Bracco Mobile Isotope Service delivers the radiotracer and infusion system to an imaging site on an as-needed basis – even if that's just one day each week to start. Any provider with a PET camera can participate in the program including community hospitals and outpatient imaging centers. Any clinician who wants to provide cardiac PET imaging can now do so while minimizing additional upfront and operating costs.

How does this service help patients?
In the past, Cardiac PET imaging was more accessible for larger academic and healthcare institutions, particularly in cities and surrounding areas. However, people that live near these institutions are not the only ones who have heart disease. Many people live in rural areas where there isn't a large population or prestigious healthcare institution nearby. Bracco believes all patients, regardless of where they live, should have access to the diagnostic power of cardiac PET imaging. The test can be done in about 30 minutes, and it can provide useful information to physicians for guiding treatment, especially when invasive options are being considered.

How do healthcare providers know whether Bracco Mobile Isotope Service is the right fit for them?
Bracco has been in the cardiac PET business for more than 30 years, and we develop a relationship and work with each site individually to understand their business. Their patient population, local reimbursement landscape, budget, and location – it all matters, and each is a factor in deciding if a part-time program like BMIS will serve their needs.

ANY CLINICIAN WHO WANTS TO PROVIDE CARDIAC PET IMAGING CAN NOW DO SO WHILE MINIMIZING ADDITIONAL UPFRONT AND OPERATING COSTS.

We equip our Nuclear Medicine Account Managers with business case tools for any type of imaging site. For instance, we use financial proformas to determine breakeven points, patient volume requirements, and which program makes sense for them. After a site has committed to working with us, regular business reviews ensure the program is successful. Over time, some practices may become candidates for full-time cardiac PET programs. Our experts become trusted advisors to our potential and existing customers.

How can providers find more information about Bracco Mobile Isotope Service?
Anyone interested in Bracco Mobile Isotope Service or our cardiac PET imaging products should visit www.cardiogen.com. From there, they can learn more on their own or use the site to find and contact their local area Nuclear Medicine Account Manager.

BRACCO
LIFE FROM INSIDE

BS43-8200H

Bracco Diagnostics

CARDIOGEN-82®
(Rubidium Rb 82 Generator)

Rx only
Please see full prescribing information.
A brief summary follows.

WARNING: HIGH LEVEL RADIATION EXPOSURE WITH USE OF INCORRECT ELUENT AND FAILURE TO FOLLOW THE ELUATE TESTING PROTOCOL

Please see full prescribing information for complete boxed warning

High Level Radiation Exposure with Use of Incorrect Eluent

Using the incorrect eluent can cause high Strontium (Sr) 82 and Sr 85 breakthrough levels (5.1)

• Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator (2.5)

• Immediately stop the patient infusion and permanently discontinue the use of the affected CardioGen-82 generator if the incorrect solution is used to elute the generator (4)

• Evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow (2.10)

Excess Radiation Exposure with Failure to Follow the Eluate Testing Protocol

Excess radiation exposure occurs when the levels of Sr 82 or Sr 85 in the rubidium Rb 82 chloride injection exceed limits. (5.2)

• Record eluate volume, including waste and test volumes. (2.5)

• Strictly adhere to the generator eluate testing protocol (2.6, 2.7)

• Stop using the generator if it reaches any of its Expiration Limits (2.8)

1 INDICATIONS AND USAGE

CardioGen-82 is a closed system used to produce rubidium Rb 82 chloride injection for intravenous administration. Rubidium Rb 82 chloride injection is indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

3 DOSAGE FORMS AND STRENGTHS

CardioGen-82 is a closed system used to produce rubidium Rb 82 chloride injection for intravenous use. CardioGen-82 consists of strontium Sr 82 adsorbed on a hydrous stannic oxide column with an activity of 3,330 MBq to 5,550 MBq (90 millicuries to 150 millicuries) Sr 82 at calibration time.

4 CONTRAINDICATIONS

CardioGen-82 is contraindicated if a solution other than additive free 0.9% Sodium Chloride Injection USP has been used to elute the generator at any time. Immediately stop the patient infusion and permanently discontinue the use of the affected CardioGen-82 generator whenever the incorrect eluent is used [*see Boxed Warning, Contraindications (4), and Warnings and Precautions (5.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 High Level Radiation Exposure with Use of Incorrect Eluent

Use only additive free 0.9% Sodium Chloride Injection USP to elute the generator. Apply the provided saline tag to the additive free 0.9% Sodium Chloride Injection USP container before use. Additives present in other solutions (particularly calcium ions) expose patients to high levels of radiation by causing the release of large amounts of Sr 82 and Sr 85 into the eluate regardless of the generator's age or prior use [*Dosage and Administration (2.1. 2.5, and 2.6, 2.7)*]. **Immediately stop the patient infusion and discontinue use of the affected CardioGen-82 generator if the incorrect eluent is used and evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow.** When solutions containing calcium ions are used to elute the generator, high levels of radioactivity are present in any subsequent eluate, even with the use of additive free 0.9% Sodium Chloride Injection USP. [*see Boxed Warning, Dosage and Administration (2.10) and Contraindications (4)*].

5.2 Excess Radiation Exposure with Failure to Follow Eluate Testing Protocol Excess radiation exposure occurs when the Sr 82 and Sr 85 levels in rubidium Rb 82 chloride injections exceed the specified generator eluate limits.

Strictly adhere to the eluate testing protocol to minimize radiation exposure to the patient. Stop using the rubidium generator when the expiration limits are reached [*see Dosage and Administration (2.6, 2.7) and (2.8)*].

5.3 Risk Associated with Pharmacologic Stress Pharmacologic induction of cardiovascular stress may be associated with serious adverse reactions such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction, and cerebrovascular events. Perform pharmacologic stress testing in accordance with the pharmacologic stress agent's prescribing information and only in the setting where cardiac resuscitation equipment and trained staff are readily available.

5.4 Volume Overload Patients with congestive heart failure or the elderly may experience a transitory increase in circulatory volume load.

5.5 Cumulative Radiation Exposure: Long-Term Risk of Cancer Rubidium Rb 82 chloride injection, similar to other radiopharmaceuticals, contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Use the lowest dose of rubidium Rb 82 chloride injection necessary for imaging and ensure safe handling to protect the patient and health care worker [*see Dosage and Administration (2.1) and (2.2)*]. Encourage patients to void as soon as a study is completed and as often as possible thereafter for at least one hour.

6 ADVERSE REACTIONS

6.1 Postmarketing Experience The following serious adverse reactions have been identified during post approval use of CardioGen-82. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Radiation Exposure High level radiation exposure to the bone marrow has occurred in some patients due to Sr 82 and Sr 85 breakthrough in the eluate when an incorrect solution was used to elute the rubidium Rb 82 generator [*see Boxed Warning and Warnings and Precautions (5.1)*].

Excess radiation exposure has occurred in some patients who received rubidium Rb 82 chloride injections at clinical sites where generator eluate testing appeared insufficient [*see Boxed Warning, Warnings and Precautions (5.2), and Dosage and Administration (2.6 or 2.7)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no data available on the use of rubidium Rb 82 chloride in pregnant women. Animal reproductive studies have not been conducted with rubidium Rb 82 chloride injection. However, all radiopharmaceuticals have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of the radiation dose. If considering rubidium Rb 82 chloride injection administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation dose from rubidium Rb 82 and the gestational timing of exposure.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of Rb 82 chloride in human milk, the effects on the breastfed infant or the effects on milk production. Due to the short half-life of rubidium Rb 82 (75 seconds), exposure of a breastfed infant through breast milk can be minimized by temporary discontinuation of breastfeeding [See CLINICAL CONSIDERATIONS]. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for rubidium Rb 82 chloride injection, any potential adverse effects on the breastfed child from Rb 82 or from the underlying maternal condition.

Clinical Considerations

Minimizing Exposure Exposure to Rb 82 chloride through breast milk can be minimized if breastfeeding is discontinued when Rb 82 chloride injection is administered. Do not resume breastfeeding until at least one hour after completion of rubidium Rb 82 chloride injection infusion.

8.4 Pediatric Use

Rubidium Rb 82 chloride injection safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

In elderly patients with a clinically important decrease in cardiac function, lengthen the delay between infusion and image acquisition [*see Dosage and Administration (2.3)*]. Observe for the possibility of fluid overload [*see Warnings and Precautions (5.4)*].

8.6 Renal Impairment

Reductions in renal function are not anticipated to alter clearance of rubidium Rb 82 chloride injection because Rb 82 decays to stable Kr 82 with a half-life of 75 seconds and Kr 82 is exhaled through the lungs.

8.7 Hepatic Impairment

Reductions in hepatic function are not anticipated to alter clearance of rubidium Rb 82 chloride injection.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility No long-term studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or to determine whether rubidium Rb 82 chloride injection may affect fertility in males or females.

17 PATIENT COUNSELING INFORMATION

Pregnancy Advise a pregnant woman of the potential risk to a fetus [*see Use in Specific Populations (8.1)*].

Lactation Advise lactating women that exposure to Rb-82 chloride through breast milk can be minimized if breastfeeding is discontinued when Rb 82 chloride injection is administered. Advise lactating women not to resume breastfeeding for at least one hour after completion of rubidium Rb 82 infusion [*see Use in Specific Populations (8.2)*].

Post-Study Voiding Instruct patients to void after completion of each image acquisition session and as often as possible for one hour after completion of the PET scan [*see Warnings and Precautions (5.5)*].

Manufactured for **Bracco Diagnostics Inc.** Monroe Twp., NJ 08831
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