



2024 RUBY-FILL® (Rubidium Rb 82 generator) Coding & Reimbursement Guide

Prepared by:



Jubilant@thepinnaclehealthgroup.com 866-369-9290

Disclaimer: Coding and reimbursement information is provided for educational purposes and does not assure coverage of the specific item or service in any given case. Information provided as part of this document is for educational purposes only and is not intended to provide legal, patient specific coding or claims submission information. Information is provided based upon the current landscape utilizing the information that is currently available.

Procedure coding should be based upon medical necessity and procedures and supplies provided to the patient. Jubilant Radiopharma and The Pinnacle Health Group make no guarantee of coverage or reimbursement of fees. Contact your local Medicare Administrator Contractor (MAC) or CMS for specific information as payment rates listed are subject to change. To the extent that you submit cost information to Medicare, Medicaid or any other reimbursement program to support claims for services or items, you are obligated to accurately report the actual price paid for such items, including any subsequent adjustments. Current Procedural Terminology numeric codes, descriptions, and modifiers are trademarks and copyrights of the AMA.

Coding

When reporting services provided, procedures must be coded correctly for claim submission to payers. The most commonly reported CPT (Current Procedural Terminology) and HCPCS (Healthcare Common Procedure Coding System) codes are listed in this guide for your reference.

2024 Physician Office Reimbursement

Myocardial Perfusion PET Imaging				
CPT	Descriptor	Physician Global		
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study	Contractor Priced		
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	Contractor Priced		
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)	Contractor Priced		
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	Contractor Priced		
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	Contractor Priced		
78492	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)	Contractor Priced		
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability)	Contractor Priced		
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	Contractor Priced		
78434	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)	Contractor Priced		

Contractor Priced: No formal fee schedule payment has been established; coverage and payment are subject to the Medicare Administrative Contractor review process.



2024 Physician Office Reimbursement

Myocardial PET Imaging Agents			
CPT	Descriptor	Physician Global Fee	
A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study, up to 45mci	Contractor Priced	
A9555	Rubidium Rb-82, diagnostic per study dose, up to 60 millicuries	Contractor Priced	

Stress Testing				
CPT	Descriptor	Physician Global Fee		
93015	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report	\$71		
93016	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; supervision only, without interpretation and report	\$20		
93017	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; tracing only, without interpretation and report	\$37		
93018	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; interpretation and report only	\$13		

Stress Testing Imaging Agents			
CPT	Descriptor	ASP Fee Schedule*	
J0153	Injection, adenosine, 1 mg	\$0.601	
J1245	Injection, dipyridamole per 10 mg (Persantine IV)	\$3.718	
J1250	Injection, dobutamine Hydrochloride, per 250 mg	\$9.848	
J2785	Injection, regadenoson, 0.1 mg (Lexiscan)	\$14.280	

Notes:

- Contractor Priced: No formal fee schedule payment has been established; coverage and payment are subject to the Medicare Administrative Contractor review process
- When required by payer, report NDC (National Drug Code) 65174-0021-10 for RUBY-FILL A9555 Rubidium Rb-82 injection, solution.
- *Payment based upon CMS Average Sales Price (ASP) file that is updated quarterly. The values provided are current as of January 2024 ASP Drug Pricing File. The most current file available can be found at the following webpage: : CMS ASP Drug Pricing Files



2024 Hospital Outpatient Reimbursement

Myocardial PET Imaging			
СРТ	Descriptor	OPPS	Physician Professional
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study	\$1,353	\$70
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	\$1,491	\$76
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)	\$1,491	\$69
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	\$1,491	\$72
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	\$2,251	\$84
78492	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)	\$1,491	\$81
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability)	\$1,851	\$90
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	\$1,951	\$99
78434	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)	Packaged	\$28



2024 Hospital Outpatient Reimbursement

Myocardial Perfusion Imaging Agents				
CPT	Descriptor	SI	OPPS	
A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study, up to 45 mCi	N	Packaged	
A9555	Rubidium Rb-82, diagnostic per study dose, up to 60 millicuries	N	Packaged	

Stress Testing				
CPT	Descriptor	SI	OPPS	
93015	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report	В	N/A	
93016	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; supervision only, w/o interpretation and report	В	N/A	
93017	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; tracing only, without interpretation and report	Q1	\$299	
93018	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; interpretation and report only	В	N/A	

Stress Testing Imaging Agents			
CPT	Descriptor	SI	OOPS
J0153	Injection, adenosine, 1 mg (do not use to report adenosine phosphate compounds)	N	Packaged
J1245	Injection, dipyridamole per 10 mg (Persantine IV)	Ν	Packaged
J1250	Injection, dobutamine Hydrochloride, per 250 mg	N	Packaged
J2785	Injection, regadenoson, 0.1 mg (Lexiscan)	N	Packaged

Notes:

- SI Status Indicator
- B Not paid in this setting
- N Items and Services Packaged with primary procedure
- Q1 Payment packaged if performed with another procedure; otherwise, separate payment

References

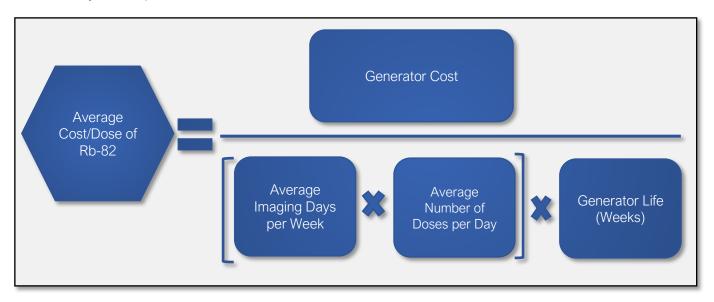
- CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Payment Systems Final Rule (CMS-1786-FC); Addendum B and ASC Addenda
- 2. CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; (CMS-1784-F); Addendum B. All MPFS Fee Schedules calculated using CF of \$32.7442 effective January 1, 2024. Please note, payments rates may be subject to change pending legislation (H.R.6683 Preserving Seniors' Access to Physicians Act of 2023).



Rubidium Cost Per Dose

With use of the RUBY Rubidium Elution System, the Sr-82\Rb-82 Generator delivers accurate doses of Rubidium-82 Chloride for patient infusions. One generator may be used for several patients over a period of several weeks. Some payers reimburse Rubidium-82 on a per dose rate, however, the Sr-82\Rb-82 Generator cost is not based on a per dose cost.

The dose cost can be calculated by dividing the cost of the generator by the number of doses drawn from the generator during the life of the generator. If the cost per dose is required by the payer, you may use the following simple calculator to determine your cost per dose. *



Generator Cost	Includes the cost of the generator, shipping costs, disposable materials, and accessories to make the generator operational
Average imaging days per week	The number of days per week that you will perform Cardiac pet studies (e.g., 1-7)
Average number of doses per day	The number of patients you expect to perform studies on for each study day multiplied by 2 to determine the doses per day (e.g., 4 patients daily x 2 doses each patient=8 doses)
Generator life (weeks)	This is the number of weeks the generator will produce doses (e.g., 5, 6, 7)
Average number of patient doses per generator	Determined by multiplying the average imaging days per week by average patients per day. Multiply this value by the generator life (weeks)

^{*}This calculation is provided as an educational document to assist with an estimated cost per dose for your specific program. The final output is based upon the information entered by the provider. Jubilant Radiopharma and The Pinnacle Health Group are providing this analysis as a guide to assist the provider to accurately calculate and report these costs.



Payer coverage

Medicare National Coverage Determination Local Coverage Determination

There is a <u>National Coverage Determination</u> <u>Cardiac PET for Perfusion of the Heart (220.6.1)</u> in place by CMS that provides coverage for cardiac PET procedures using Rubidium Rb-82 Medicare beneficiaries.

This NCD provides detailed coverage criteria for Cardiac PET studies using Rubidium Rb-82 and related procedures. The following requirements apply:

- The PET scan, whether at rest alone or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive.

A Local Coverage Determinations (LCD) and/or Local Coverage Articles (LCA) may be issued by the assigned Medicare Administrative Contractor (MAC) of a given geographic jurisdiction.

The LCDs will specify the clinical criteria that must be met for a service to be considered reasonable and medically necessary while LCAs will outline appropriate HCPCS, CPT and ICD-10 coding.

You must first determine the appropriate Medicare Administrator Contractor (MAC) for your location. This information can be located on the CMS website: Who are the MACs.

Once you determine your appropriate MAC you may identify coverage policies at the following site:

Medicare Coverage Database Search

In all cases, the PET study must be medically indicated and documented in the patient medical record.

Medicaid

Each state administers this program for beneficiaries within the state. Coverage will vary and prior authorization requirements may apply. Medicaid information by state can be located at www.medicaid.gov

Managed Care and Commercial Payers

Many private insurance plans, including both managed care and commercial, will publish coverage guidelines that detail criteria for coverage of Cardiac PET studies. These policies may be accessed on the company's website.

Each patient plan is unique, and coverage and coverage criteria will vary by plan. Most managed care plans and many commercial plans will require prior authorization for all imaging procedures.

It is recommended that you confirm coverage and the plan requirements for each patient prior to performing studies.



Jubilant Radiopharma Reimbursement Support Center

Jubilant Radiopharma provides a comprehensive support program to assist providers in obtaining appropriate reimbursement for RUBY-FILL®.

Our Reimbursement Support Center is staffed by Certified coders who are ready to support you with questions regarding:

General reimbursement

- Appropriate coding for studies and related procedures
- Coverage policy information
- Payment related questions/issues
- Assist with cost per dose calculations
- Claim underpayment or Appeal support

Prior authorization

- Determine prior authorization requirements
- Review prior authorization documentation
- Support physicians and patients through the prior authorization process
- Assist with prior authorization denials

Claim appeals

- Support physicians and patients with appeal process
- Assist with appeal letters and documentation necessary to approach payers with appropriate coverage requests
- Outline appeal steps and peer to peer opportunities

Specialized services for new and existing cardiac pet programs

- Consultation and education for new and existing cardiac PET programs
- Financial analysis program review

Contact our Reimbursement Support Team Monday-Friday: 8:30am-6:00pm EST at:

Jubilant@thepinnaclehealthgroup.com or

1-866-369-9290







Myocardial Perfusion Positron Emission Tomography (PET) Preferred and Recommended¹

The American Society of Nuclear Cardiology (ASNC) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) encourage providers to consider this imaging option for appropriate clinical situations.

Properties of Myocardial PET				
• H	ligh diagnostic accuracy	•	Short image acquisition time	
• C	Consistent high-quality images	•	Quantification of myocardial blood flow	
• L	ow radiation exposure	•	Strong prognostic power	

Preferred Test

Myocardial perfusion PET is a first-line preferred test for patients:

Unable to complete a diagnostic-level exercise stress imaging study,

With known or suspected CAD, and

Who meet appropriate criteria for stress-imaging test

There are <u>no clinical scenarios</u> where PET should not be considered a preferred test for patients who meet appropriate criteria for a stress-imaging test and who require pharmacologic stress.

Recommended Test

Patients with suspected active CAD who meet appropriate criteria for a stress-imaging test and who <u>also meet one</u> <u>or more of the following criteria</u>

Poor quality prior stress imaging study

High-risk patients

Young patients with established CAD

- Patients in whom myocardial blood flow quantification is needed
- Body characteristics that commonly affect image quality

Click <u>here</u> for the full Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET

¹American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. J. Nucl. Cardiol. 23, 1227–1231 (2016). https://doi.org/10.1007/s12350-016-0626-9



RUBY-FILL Indications for Use:

RUBY-FILL® Rubidium Rb 82 Generator is a closed system used to produce rubidium Rb 82 chloride injection for intravenous use. Rubidium Rb 82 chloride injection is a radioactive diagnostic agent 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.

Important Safety Information:

WARNING: HIGH LEVEL RADIATION EXPOSURE WITH USE OF INCORRECT ELUENT AND FAILURE TO FOLLOW QUALITY CONTROL TESTING PROCEDURE

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) break-through 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 discontinue the use of the affected RUBY-FILL 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 (2.9)

Excess Radiation Exposure with Failure to Follow the Quality Control Testing Procedure

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

- Strictly adhere to the generator quality control testing procedure (2.6)
- Stop using the generator if it reaches any of its Expiration Limit. (2.7)

The risk information provided here is not comprehensive. Please see Full Prescribing Information including BOXED WARNING at www.rubyfill.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088

2024-US-RUBY-00001

