PETITION FOR AN ADJUSTED NEED DETERMINATION FOR ONE DEDICATED CARDIAC MOBILE PET SCANNER

Petitioner

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Requested Change

Alliance Healthcare Services Inc. (Alliance) respectfully petitions the State Health Coordinating Council (SHCC) to adjust the 2023 State Medical Facilities Plan (SMFP) to include a need determination for one dedicated cardiac mobile PET scanner for the statewide Mobile PET Service Area for the purpose of providing improved patient access and image quality.

On September 1, 2021, Akumin acquired Alliance HealthCare Services, including Alliance HealthCare Radiology and Alliance Oncology. The combined organization forms the most comprehensive provider of outpatient Radiology and Oncology services to health systems, hospitals, physicians, and communities in the United States.

Reasons for the Requested Adjustment

Alliance has identified multiple North Carolina hospitals with the need for dedicated cardiac mobile PET scanner services to augment their existing fixed PET scanners and to complement existing mobile PET host sites. Fixed PET scanners at tertiary hospitals and academic medical centers are primarily used for oncology procedures which utilize different protocols and radiotracers than cardiac PET procedures. Having a dedicated cardiac PET scanner would enable a facility to schedule multiple cardiac PET procedures without disruption to the higher-volume PET oncology utilization. This arrangement would allow hospitals with fixed PET scanners to implement cardiac PET procedures with a separate dedicated

staff and coordinate the cost-effective procurement of the cardiac radiopharmaceuticals. There are also multiple hospital locations that are currently utilizing mobile PET service for oncology procedures that could also support the separate implementation of mobile cardiac PET, which would improve patient scheduling and access.

Many hospitals throughout North Carolina currently provide single photon emission computed tomography (SPECT) for cardiac imaging procedures. As these hospitals consider their future equipment needs, cardiac PET scanners may be a more effective alternative over the traditional SPECT systems. Cardiac PET provides improved accuracy, less radiation and increased efficiency in the detection of coronary artery disease (CAD) compared to current modes of nuclear stress testing. Cardiac PET procedures also provide superior image quality as compared to SPECT, with fewer imaging artifacts, as well as high spatial resolution and quantitative estimates of blood flow. Cardiac PET procedures having long been reimbursed by Medicare, and the business model for cardiac mobile PET indicates that a facility that performs a minimum of four procedures per day would be sustainable. Implementing a dedicated cardiac mobile PET scanner offers a means for hospitals to shift some cardiac procedures from SPECT to PET and build utilization to support their potential acquisition of fixed cardiac PET.

Cardiac PET radiotracers are becoming more readily available with the availability of mobile generators. As seen in Attachment A, Alliance has support from Cardionavix to provide a mobile generator onsite to accompany the dedicated cardiac mobile PET scanner. The generator and all necessary equipment are delivered as needed, so the host site pays only for the days they wish to image patients. This arrangement can be ideal for healthcare providers imaging on a part-time schedule, those located in less populous areas, or those seeking to ramp up and grow into a full-time traditional generator delivery schedule as their number of procedures increases.

As seen in Attachment B, the Joint Position Paper by The American Society of Nuclear Medicine and Society of Nuclear Medicine and Molecular Imaging discusses the underutilization of myocardial perfusion PET relative to its wide availability in the United States and its demonstrated advantages for patients being assessed for suspected clinically important CAD. For the reporting year ending September 30, 2021, total PET utilization for fixed and mobile PET combined in North Carolina increased by 8.4 percent over the previous year. Based on Alliance's experience, fixed and mobile PET services at most facilities throughout North Carolina are primarily focused on providing oncology procedures. Simply put, the high demand for oncology PET procedures in North Carolina continues to overshadow the opportunity and need to expand access to cardiac PET.

This petition for one dedicated cardiac mobile PET scanner is similar to previously approved petitions and policies for specialized MRI scanners. For example, Table 17E-3 of the Proposed 2023 State Medical Facilities lists specialized MRI scanners including Cardiovascular, Pediatric Use, Dedicated Breast MRI, and Radiation Oncology, and Intraoperative. These specialized MRI scanners are needed to serve patients that meet specific criteria and require specialized staffing and resources. Similarly, the dedicated cardiac mobile PET scanner would focus on serving patients that meet specific selection criteria, including patients with a history of myocardial infarctions and those being considered for a revascularization procedure. The dedicated cardiac PET would be used for myocardial perfusion, for assessment of myocardial blood flow in post heart transplant patients, and for cardiac inflammation imaging.

Adverse Effects if the Adjustment is Not Made

Without the adjusted need determination for one dedicated cardiac mobile PET scanner, access to cardiac PET imaging will remain severely constrained and inequitable. Because the vast majority of fixed and mobile PET scanners perform only oncology procedures, the opportunity to expand access to cardiac PET procedures is largely undeveloped. The adjusted need determination would give providers an opportunity to submit competitive Certificate of Need applications to demonstrate the reasonableness of their projections and obtain more widespread support.

Alternatives Considered

Alliance considered the option of maintaining the status quo of having two existing mobile and one approved PET scanner, but this would not be an effective strategy because once the approved scanner is implemented, the combined utilization of the existing and approved host sites will fully utilize these three scanners for just oncology procedures. Furthermore, it would not be feasible for Alliance to implement its 2021 approved mobile PET as a dedicated cardiac unit because the vast majority of existing host sites need additional days of service for oncology PET procedures.

Proposed Adjustment Would Not Result in Unnecessary Duplication

Alliance's request for an adjusted need determination for one dedicated cardiac mobile PET scanner would not result in unnecessary duplication of services because:

- The 2023 SMFP does not include a mobile PET methodology to indicate that the proposed adjustment for a dedicated cardiac mobile PET scanner would have any negative impact on the utilization of other fixed or mobile PET providers.
- The potential to shift imaging utilization from traditional SPECT (nuclear medicine) cardiac procedures to cardiac PET is justified because the images are more accurate and involve less radiation exposure for patients. SPECT equipment is not a Certificate of Need regulated health service unless the project exceeds the capital cost threshold.
- As seen in the Proposed 2023 SMFP, Alliance's two existing mobile PET scanners performed a combined 7,823 annual procedures, demonstrating that when it's third mobile PET is implemented, the three scanners will already be performing at over 100 percent capacity (based on 2,600 annual procedures per scanner).
- PET utilization in North Carolina continues to increase at a strong rate, and additional fixed and mobile PET scanners are pending development, so it is very unlikely that the development of a dedicated cardiac mobile PET scanner would lead to unnecessary duplication of services.

Request is Consistent with the Basic Principles

The requested adjustment is consistent with the Basic Principles of the State Medical Facilities Plan regarding safety, quality, access and value. The proposed dedicated cardiac mobile PET will be operated in accordance with the specific Radioactive Material (RAM) Licensing requirements by the DHSR Radiation Protection Section, Radioactive Material Branch. Alliance is also committed to help host sites obtain ACR accreditation. Patient safety and quality of care are integral to the initial regulatory approval process. Alliance currently provides extensive services in support of excellent quality and safety for mobile PET services throughout North Carolina including:

- Radioactive Materials License and Accreditation Support
- Training and Continuing Education
- Information Technology
- PET Maintenance Services
- Transportation and Truck Maintenance

Access to PET services would be enhanced with the approval of the requested adjustment and the development of a dedicated cardiac mobile PET scanner. North Carolina facilities and patients are currently underserved due to the limited scope of service stemming from scheduling and staffing issues and limited availability of radiopharmaceuticals with a short half-life. Alliance is committed to providing mobile PET services to all appropriate persons, regardless of race, color, national origin, disability, age, or ability to pay.

A dedicated cardiac mobile PET scanner would provide increased value to facilities and patients because the investment in the equipment and resources would be spread over multiple facilities in support of increased productivity. Hospitals with fixed PET scanners could implement the dedicated cardiac mobile PET service to enhance their scheduling productivity and provide higher quality cardiac imaging studies. The ability to offer these more advanced imaging modalities could also strengthen cardiologist recruitment.

Summary

Alliance believes that approval of this petition to add an adjusted need determination for one dedicated cardiac mobile PET scanner would expand access to high quality cardiac imaging services in response to the growth and aging of the North Carolina population. While the Proposed 2023 SMFP does not have a methodology to demonstrate a specific deficit for mobile PET scanners, the need to expand imaging capabilities for CAD is widely supported. Alliance welcomes comments from hospitals and other providers and appreciates the thoughtful consideration of this request.

ATTACHMENT A

Mr. Daniel Stone
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RE: Dedicated Cardiac Mobile PETCT Scanner

Dear Mr. Stone,

I understand that Alliance Healthcare Services Inc. intends to submit for an adjusted need determination for a dedicated mobile cardiac PET scanner to serve North Carolina facilities. Our company, CardioNavix, LLC, fully supports this petition.

In North Carolina, as elsewhere, coronary artery disease (CAD) is the leading cause of death in both men and women. A critical element of managing CAD is early detection, and PET with Rubidium-82 (Rb82) has proven to be a superior tool for the early and accurate detection of disease while offering lower radiation exposure and greater downstream cost savings to health systems than alternative testing options. The number of cardiac PET programs around the United States continues to grow year over year as healthcare providers seek to provide the best technology and radiotracer availability is expanded.

Today and tomorrow, Cardiac PET promises to play the leading non-invasive diagnostic role on the pathway toward a future of accurate, comprehensive, personalized, and targeted cardiovascular medicine. CardioNavix stands ready to support Alliance's mission of expanding access to this advanced imaging modality to more practices. We have the capabilities, licensure, and regulatory approvals to provide mobile Rb82 for PET myocardial perfusion imaging (MPI) to your facility location(s) in coordination with the Alliance mobile PETCT scanner service.

Please let me know if you have questions or need additional information.

Sincerely,

Brendon Loiselle
Vice President, CardioNavix

ATTACHMENT B

ASNC/SNMMI POSITION STATEMENT

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY AND SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING JOINT POSITION STATEMENT ON THE CLINICAL INDICATIONS FOR MYOCARDIAL PERFUSION PET

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PREAMBLE

Many patients with suspected or known coronary artery disease (CAD) benefit from the information provided by a noninvasive cardiac imaging test. Cardiac imaging tests can provide information regarding the presence, extent, and severity of CAD, estimate risk for early and late major adverse cardiac events, and assist in determining the most appropriate treatment, including medical therapy and/or coronary revascularization. Valuable information can also be provided from a normal scan result that can obviate the need for further cardiac tests, reduce unnecessary medication expenses, lead to expeditious referrals for assessment of other causes of symptoms, and relieve anxiety over potential life-threatening etiologies for symptoms.

An important goal of imaging is to provide a high quality appropriate test for the right patient at the right time. There needs to be confidence and certainty in distinguishing normal from an abnormal study, and avoidance of equivocal interpretations which would result in redundant testing, delay of timely care, and increased downstream cost. This is consistent with the Centers for Medicare & Medicaid Services (CMS) implementation of quality initiatives to assure quality health care. These goals include effective, safe, efficient, patient-centered, equitable, and timely care. The imaging properties of myocardial perfusion positron emission tomography (PET) meet all of these quality goals. PET myocardial perfusion imaging is effective (high diagnostic accuracy), safe (low radiation exposure), efficient (short, 5 min image acquisition times), and patient-centered (accommodates ill or higher-risk patients as well as those with large body habitus), providing equitable (independent of patient characteristics and condition) and timely care.

Among available noninvasive cardiac imaging options, the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging have noted significant underutilization of myocardial perfusion PET relative to its demonstrated advantages for patients being assessed for suspected clinically important CAD, and to its current wide availability in the United States. The purpose of this joint Society Recommendation is to succinctly summarize the properties that make myocardial perfusion PET most useful in the diagnosis and management of the CAD patient, and to provide general guidance as to when it should be considered for optimal patient care.

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IMPORTANT PROPERTIES OF MYOCARDIAL PERFUSION PET

1. **High diagnostic accuracy:** Myocardial perfusion PET has high sensitivity and specificity for angiographically significant obstructive CAD, and has been shown in meta-analyses to outperform other noninvasive approaches. Its high sensitivity improves recognition of multivessel CAD, and its high specificity improves recognition of absence of multivessel CAD. Furthermore, the combination of information gained from consistent and high-quality perfusion images, peak stress regional and global contractile function, and quantitation of myocardial blood flow permits identification of very low-risk patients that can obviate the need for further cardiac tests, reduce unnecessary medication expenses, lead to expeditious referrals for assessment of other causes of symptoms, and relieve anxiety over potential life-threatening etiologies for symptoms. The presence of coronary artery calcium can also be identified when patients are imaged using a PET/CT scanner, ensuring that an otherwise normal perfusion scan is not misinterpreted by patients, and referring physicians as indicating absence of any CAD.
2. **Consistent high-quality images:** Myocardial perfusion PET images have high myocardial counts, high spatial and contrast resolution, high signal-to-noise ratio, and accurate and reliable correction for the effects of tissue attenuation and scatter. Image quality is relatively unaffected by body shape or size, distinguishing PET from all other cardiac imaging modalities.
3. **Low radiation exposure:** A complete rest-stress myocardial perfusion PET scan routinely exposes patients to less than 5 mSv and as little as 1 mSv effective dose using 3D imaging protocols, well below levels known to be associated with long-term adverse effects, and low in comparison to most radiation-based cardiac assessments. This is an important safety concern for patients with established CAD, who are likely to be repetitively exposed over their lifetimes to radiation-based studies, and to younger patients with longer time frames for cancers to develop.
4. **Short acquisition protocols:** A complete rest/stress study can be acquired in less than one hour if rubidium-82 is used. In addition to the obvious convenience to patients, this is an advantage for acutely ill or high-risk patients, such as those in emergency departments or acute chest pain units. The 5-minute acquisition times are also helpful for those patients who find it difficult to remain still for more than a few minutes, reducing the likelihood of nondiagnostic scans due to patient motion artifact.
5. **Quantification of myocardial blood flow:** Blood flow quantification at rest and stress is used to measure myocardial flow reserve. It allows verification of adequate stress response, further improving interpretation confidence. Regional flow reserve shows the physiological significance of epicardial CAD, analogous to invasive fractional flow reserve (FFR). In the absence of epicardial CAD, flow reserve allows the assessment of microcirculatory function. The ability to routinely quantify myocardial blood flow in ml/min/gram is unique to PET, improves accuracy, risk stratification, and patient selection for interventions.
6. **Strong prognostic power:** Myocardial perfusion PET, particularly when myocardial blood flow data are included, provides high discrimination between different levels of risk in all patient populations for whom myocardial perfusion imaging is appropriate, including obese and nonobese people, men and women, diabetics, and patients with renal dysfunction.

All of the above properties are generally applicable to both dedicated PET and PET/CT scanners. In the case of the increasingly used PET/CT scanners, in which low-dose CT is used to generate a transmission map for attenuation correction, coronary artery calcium can also be identified, without any additional radiation exposure.

CLINICAL INDICATIONS

The American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging have concluded that the properties of myocardial perfusion PET according to the published literature are sufficient to advance recommendations for its use in clinical practice. These recommendations are general in intent and should not be interpreted as either inclusive or exclusive of specific clinical scenarios. However, they reflect the current understanding based on extensive clinical investigations as to when myocardial perfusion PET will provide best clinical value.

i. **Preferred:** Rest-stress myocardial perfusion PET is a first line preferred test for patients with known or suspected CAD who meet appropriate criteria for a stress imaging test and are unable to complete a diagnostic level exercise stress imaging study. There are no clinical scenarios 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.

ii. **Recommended:** Rest-stress myocardial perfusion PET is recommended for patients with suspected active CAD, who meet appropriate criteria for a stress imaging test, and who also meet one or more of the following criteria:

   a. Prior stress imaging study that was of poor quality, equivocal or inconclusive, affected by attenuation artifact, or discordant with clinical impressions or other diagnostic test results including findings at coronary angiography.
   b. Body characteristics that commonly affect image quality. Some examples include large breasts, breast implants, obesity (BMI greater than 30), protuberant abdomen, chest wall deformities, pleural effusions, and inability for proper body positioning such as inability to position arms outside of a SPECT scanner's field of view.
   c. High-risk patients in whom diagnostic errors carry even greater clinical implications. Some examples include chronic kidney disease stage 3, 4 or 5; diabetes mellitus; known or suspected potentially high-risk CAD such as left main, multivessel, or proximal LAD disease or when extensive coronary disease is known such as following coronary bypass surgery or coronary interventions; suspected transplant coronary vasculopathy; when ischemia is suspected in patients with left ventricular dysfunction; and patients for whom revascularization carries increased morbidity and mortality risk.
   d. Young patients with established CAD who are anticipated to need repeated exposures to radiation-associated cardiac imaging procedures, in order to minimize accumulated life-time exposure.
   e. Patients in whom myocardial blood flow quantification is identified by clinicians to be a needed adjunct to the image findings, to better identify or exclude multivessel CAD, for improved risk stratification, and when assessment of microcirculatory function is needed for clinical decision making.

CONCLUSION

The purpose of this joint Society Position Statement is to highlight the attributes that make rest/stress myocardial perfusion PET both **Preferred** and **Recommended** in the era of high value initiatives for appropriate patients. Myocardial perfusion PET image quality, high diagnostic accuracy that is relatively independent of body habitus, ability to accurately risk stratify patients with a wide array of clinical presentations, short acquisition times, safety by virtue of low radiation exposure, and its unique ability to quantify myocardial blood flow are all significant and clinically important properties. The American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging encourage providers to consider this imaging option for appropriate clinical situations.

DISCLOSURES

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Research Grant: Astellas, GE Healthcare
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Salaried Employee/Owner: CVIT

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Note: The American Society of Nuclear Cardiology maintains a comprehensive and up-to-date listing of key references in myocardial perfusion PET that can be accessed at www.asnc.org