



Accountable Care Calls for High-quality Imaging from Nuclear Cardiology  
*Payment Reform is Forging New Attributes for What Constitutes a Well-rounded Modality*

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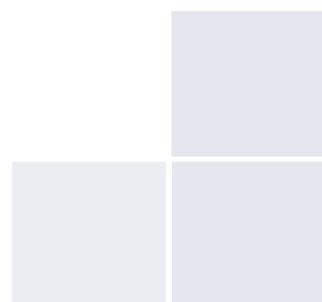
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## EXECUTIVE SUMMARY

- New bundled payment structures for complete episodes of care are going to be introduced and will expand, regardless of any action that may be taken by the new US administration concerning the Affordable Care Act.
- Cardiovascular conditions, most of which rely heavily on imaging, are at the frontlines of this ongoing payment reform. Imaging procedures deemed appropriate will have to contribute and show value in the patient care pathways.
- This will change physicians' expectations of nuclear imaging, which comes in at the front end or at later stages of the episodes. It will also directly impact the attributes that constitute the best nuclear imaging equipment for accountable care.
- Nuclear imaging providers will need to optimize their early diagnosis and prognosis capabilities, provide more actionable guidance and risk stratification in patient management, be evenly accessible to the population, and be highly cost-effective.
- Digirad's X-ACT+ checks the mark on all of the attributes that will empower nuclear imaging providers in the transition. The solution further has a price point and total cost of ownership that align well with the changing economics of imaging.



## FOREWORD

If the ideal nuclear cardiology modality existed, we would probably not be witnessing such a considerable degree of innovation in this clinical area as we are today. A number of imaging modalities are in the race to become the new standard of care. However, in reality, none come without their fair share of tradeoffs and limitations.

The diagnostic cardiology modality armamentarium is rich and getting richer as each one of its constituents keeps pushing its limits forward—from single-photon emission computed tomography (SPECT) to positron emission tomography (PET); from magnetic resonance (MR) to contrast-enhanced ultrasound (CEUS); and with emerging techniques such as intravital microscopy (IVM) or fluorescence molecular tomography (FMT), among others.

If you ask any physician what they would expect from their nuclear cardiology imaging equipment—high resolution, high specificity, high sensitivity, short procedure times, low cost, adequate reimbursement, safety and comfort for their patients, wide access to the population, or solid risk stratification and prognosis—the most likely answer will be: **“All of the above!”**

What constitutes a well-rounded modality for today’s healthcare environment; in other words, what attributes really matter toward the Triple Aim of improving the patient experience of care, improving the health of populations, and reducing the per capita cost of healthcare?

## VALUE-BASED PAYMENTS: THE TRAIN HAS LEFT THE STATION

A value-based environment is setting in place in the US healthcare system, advancing slowly, but surely. In fact, the past 18 months have brought dramatic change in the way payers and providers assess the appropriateness and the value of various healthcare services, especially in the high-cost area of advanced diagnostics.

**“The train has left the station,”** said Cathie Biga, JD Georgia L. Hearn, in the session “MACRAnomics: Is Your Practice/System Ready?” that she presented at the 2016 annual meeting of the American Society of Nuclear Cardiology in Boca Raton, Fla., in front of a packed audience.

Indeed, the Medicare Access and CHIP Reauthorization Act (MACRA), which was passed with bipartisan support in 2015, has already achieved many of the initial goals of its new quality payment program. Notably, it has surpassed the mid-2016 target threshold of 85% that was set by the Centers for Medicare & Medicaid Services (CMS) for tying the Current Procedural Terminology (CPT) codes of reimbursement claims to quality metrics from the Physician Quality Reporting System (PQRS).

**“We are already close to 100%,”** Biga said, which indicates that PQRS is well under way to being rolled into the new Merit-based Incentive Payment System (MIPS), the pay-for-performance framework for US physicians

## CARDIOLOGY AND IMAGING AT THE FRONTLINES OF PAYMENT REFORM

This rapid MACRA rollout has direct and significant implications on the cardiology specialty. As part of CMS' Bundled Payments for Care Improvement (BPCI) initiative,<sup>1</sup> 48 bundled payments for complete episodes of care are at various stages of being designed, piloted or implemented.

Out of the 48, one—the hip-and-knee replacement bundle of the Comprehensive Care for Joint Replacement Model—was already put in place in 2016. The next two in line are cardiology payment bundles, one for acute myocardial infarction (AMI) and one for coronary artery bypass graft (CABG). These seem to be well on track to being implemented in the near term.

As for the mid-term outlook, one cannot help but note that 14 out of the 48 bundled payments currently part of the BPCI initiative pertain to cardiovascular conditions (Fig.1). In addition, most, if not all, of these episodes of care are imaging-intensive. In fact, they invariably include one or more medical imaging procedures, whether diagnostic or interventional, as a core component of the episode.

In addition to these major CMS initiatives, a similar transition to value-based payments is also occurring on the private payor side. A large—and growing—number of initiatives are well under way on the part of accountable care organizations, large employers, and payer-provider entities, all of which are experimenting or moving ahead with new capitated or bundled payment structures.

**Figure 1: Cardiology accounts for nearly one in three episodes of care in CMS' Bundled Payments for Care Improvement (BPCI) initiative.**

1. Acute myocardial infarction	25. Double joint replacement of the lower extremity
2. Atherosclerosis	26. Fractures femur and hip/pelvis
3. Automatic implantable cardiac defibrillator generator or lead	27. Gastrointestinal hemorrhage
4. Cardiac arrhythmia	28. Gastrointestinal obstruction
5. Cardiac defibrillator	29. Hip and femur procedures except major joint
6. Cardiac valve	30. Lower extremity and humerus procedure except hip, foot, femur
7. Congestive heart failure	31. Major bowel
8. Coronary artery bypass graft surgery	32. Major joint replacement of the lower extremity
9. Major cardiovascular procedure	33. Major joint replacement of upper extremity
10. Other vascular surgery	34. Medical non-infectious orthopedic
11. Pacemaker	35. Medical peripheral vascular disorders
12. Pacemaker device replacement or revision	36. Nutritional and metabolic disorders

<sup>1</sup> <https://innovation.cms.gov/initiatives/bundled-payments/>

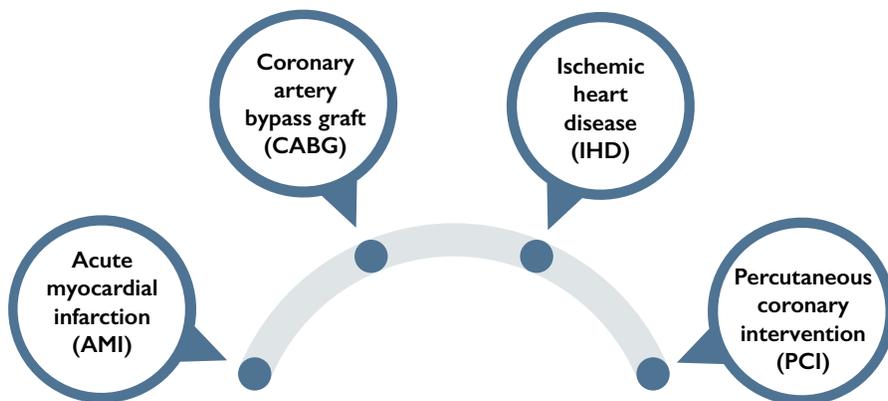
13. Percutaneous coronary intervention	37. Other knee procedures
14. Transient ischemia	38. Other respiratory
15. Amputation	39. Red blood cell disorders
16. Back and neck except spinal fusion	40. Removal of orthopedic devices
17. Cellulitis	41. Renal failure
18. Cervical spinal fusion	42. Revision of the hip or knee
19. Chest pain	43. Sepsis
20. Chronic obstructive pulmonary disease, bronchitis/asthma	44. Simple pneumonia and respiratory infections
21. Combined anterior posterior spinal fusion	45. Spinal fusion (non-cervical)
22. Complex non-cervical spinal fusion	46. Stroke
23. Diabetes	47. Syncope and collapse
24. Esophagitis, gastroenteritis and other digestive disorders	48. Urinary tract infection

### IMPLICATIONS ON NUCLEAR CARDIOLOGY SERVICE LINES

As is the case for radiologists, the large majority of cardiologists also will be part of the MIPS track of the Quality Payment Program, and not the Advanced Alternative Payment Models (APM). These two physician specialties are in care areas that are amongst the most prone to transformation under healthcare payment reform. As such, they will be measured on their contributions to the quality, the outcomes and the cost efficiency of the various episodes of care that they provide. Moreover, soon they will be financially rewarded or penalized based on these measurements.

Nuclear cardiology, as a sub-specialty of cardiology and/or nuclear medicine, will be impacted strongly by the new payment models because it is deeply entrenched in most of the care pathways being transformed. As a case in point, nuclear SPECT is established as the front-line modality in several of these episodes of care (Fig. 2), where it serves the key function of risk-stratifying patients and determining the clinical course of action, in addition to being established as a second-line modality in a number of other care episodes.

Figure 2: Care episodes in which nuclear SPECT is established as the front-line modality under most of the current clinical protocols.



## ATTRIBUTES OF A WELL-ROUNDED IMAGING MODALITY IN ACCOUNTABLE CARE

In the value-based healthcare environment that is forging ahead, a radical change in imaging modalities is expected. For instance, the technical specifications of certain high-cost/high-payment modalities will no longer suffice alone to make them the favored choice as under the fee-for-service paradigm. A new set of core attributes will determine how the different tradeoffs of each modality are sorted out by comparing and contrasting them against one another, and making the most appropriate choices for patient care.

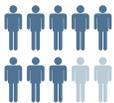
In line with the Triple Aim of healthcare reform, the top attributes that distinguish the most appropriate imaging modality in the new environment revolve around value, quality and cost efficiency. More specifically:



**1. Powerful detection**, early diagnosis and prognosis capabilities through robust disease characterization.



**2. Strong risk stratification potential** and actionable guidance in patient management decisions, notably in the initiation, evaluation of responsiveness, monitoring, and guiding of therapeutic interventions.



**3. Broad-based access to the population** so that care pathways can be standardized across a payer's or a health system's catchment region.



**4. Cost-effectiveness of its value contribution** to the total episode of care, accounting for savings from downstream impact on utilization, such as “gate-keeping” invasive or expensive procedures.



**5. Personalization potential** of the procedure's protocol as well as the patient management decisions that it supports, contributing to the broader transition to precision medicine.

Collectively, these attributes ensure a positive contribution of a given modality to risk-adjusted health outcomes and to the risk-adjusted total cost of care in a health system. These are the most crucial elements to consider today.

“Do we want to be better at detecting disease, or do we want to be better at influencing outcomes?” This question, raised by Mouaz H. Al-Mallah, MD, FASNC, during the ASNC session “PET-MPI vs. SPECT-MPI: Necessity or Extravagance?” is a great illustration of the new rules of the game in the inter-modality competition. In essence, Mallah rightly questions whether the incremental improvement in diagnostic accuracy of PET MPI compared to SPECT MPI will be justified in the new healthcare environment, considering the cost differential, spotty access, and complex logistics of cardiac PET programs compared to cardiac SPECT.

## **PERFECT ALIGNMENT OF HIGH-END SPECT EQUIPMENT ATTRIBUTES**

Today, a limited number of market offerings constitute the high-end product segment for SPECT imaging equipment. Compared to the large number of legacy gamma camera equipment in the installed base, many of which are 10 or even 20 years old, these state-of-the-art solutions provide attributes that match closely with the imperatives of value-based care:

**1. Solid-state detector technology.** Whether they use CZT (direct conversion) or CSi (indirect conversion), the modern-day, solid-state detectors represent a huge technological leap forward compared to previous-generation analog “Anger” detectors, especially for cardiac use. They allow for key features such as smaller and lighter gantries, faster imaging procedures, increased ease of use, and improved repairability.

**2. Attenuation correction (AC).** AC improves the quality of SPECT imaging. Improved image quality correlates directly with a higher rate of definitive diagnoses, which translates into effective stratification and management of patients, and downstream savings in the care pathway. In addition, the method is proven to contribute to an increase in true-negative rates. This can often eliminate the need for the rest portion of a stress-rest examination, in which case procedure times are cut at least by half. Some of the vendors of high-end SPECT equipment implement AC via a previously acquired CT study, which is not always achievable. Others propose a hybrid SPECT-CT to fulfil this objective, which requires a substantial additional capital investment. Only one vendor, Digirad, has developed AC capabilities that do not require a full-fledged CT platform or the availability of a CT prior.

**3. Dose reduction.** The latest generation of high-end SPECT imaging equipment is far more dose-efficient than its predecessors. Especially when combined with AC, accurate normalcy rates with these systems increase significantly without a penalty on dose. At a time when the dose requirements of every procedure from ionizing imaging modalities is being scrutinized, and while the nuclear imaging industry expects new mandates and guidelines to be introduced in the SPECT area, the best practice is to take on a proactive approach to dose reduction and dose optimization.

## STRIKING THE RIGHT BALANCE WITH DIGIRAD'S NEW X-ACT+

- **CSi: the optimal solution:** In comparing the two solid-state technologies using CSi and CZT, CSi has the advantage of being much more cost-effective, which raises the question of whether the incremental energy resolution of CZT warrants the significant premium price that it entails. In addition, despite their claims that CZT technology is superior, its advocates have had to implement alternate imaging methods in order to reduce the amount of CZT used in the detector, which exacerbates the imaging limitations for heavy patients.
- **Fluorescence X-ray attenuation correction (FAC):** This low-dose technique is unique to Digirad and provides a fully integrated approach to attenuation correction in SPECT imaging. It allows providers to obtain the benefits of AC as part of a unique imaging session, without the overhead caused by other approaches such as hybrid SPECT-CT imaging. This also allows positioning patients for accurate co-registration of emission and transmission scans.



- **No-compromise patient access:** The X-ACT+ allows customized imaging protocols with precisely the right balance between dose and time for each individual patient. This exam personalization potential helps overcome one of the main limitations of SPECT imaging in general, namely the imaging of large patients, who tend to be sent to PET instead. By supporting a much wider range of patients through the automated TruACQ Count-Based Imaging software, X-ACT+ eliminates the need to segregate patients based on their weight.
- **Optimized cardiac imaging:** The TruACQ feature combines with Digirad's detector geometry, which is developed from the ground-up for optimal cardiac imaging. Indeed, X-ACT+ is designed for cardio-centric upright imaging with an adjustable orbit radius of the heads, which allows for imaging patients of any size or body habitus. TruACQ, therefore, contributes simultaneously to large patient imaging as well as dose reduction, while still providing the optimal image based on count volume. Essentially, TruACQ takes away the guess work from the nuclear medicine technologist (NMT) and immediately calculates the optimal acquisition time, regardless of size or dose.

- **Empowered physicians:** The X-ACT+ platform is configured with three detector heads. Multi-head imaging significantly increases the number of simultaneous photon counts, allows covering the entire volume of the heart with faster image acquisition times, and uses lower amounts of dose. This essentially puts the nuclear physician in the driver's seat to trade speed for dose or vice versa, and devise the right image acquisition protocol for each individual patient.
- **Patient ergonomics:** One of the key indicators of quality that virtually every health system is measuring and being evaluated on today is HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems), the patient satisfaction survey made mandatory by CMS. This metric stresses the importance of providing a pleasant patient experience at every step of the healthcare journey. The new and improved patient ergonomics of the X-ACT+, which is designed to help increase patient comfort, shorten procedure times and reduce retakes, can act as a solid contributor to satisfaction scores of patients undergoing nuclear imaging.



## NEXT STEPS



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