



# Pennsylvania

CHAPTER

**Chapter Executive/Office**  
Maria B. Elias  
777 East Park Drive  
PO Box 8820  
Harrisburg, PA 17105-8820  
(717) 909-2698  
FAX – (717) 558-7841  
melias@pamedsoc.org  
www.pcacc.org

November 1, 2010

Donald Fischer, M.D.  
Senior Vice President and Chief Medical Officer  
Highmark  
120 Fifth Avenue  
Pittsburgh, PA 15222-3099

**Executive Council**

**President**

Governor, Eastern PA  
John U. Doherty, MD, FACC

**Vice President**

Governor, Western PA  
Rene Alvarez, Jr., MD, FACC

**Secretary/Treasurer**

Michael A. Rossi, MD, FACC

**Immediate Past Governor, Western PA**

Daniel Edmundowicz, MD, FACC

**Immediate Past Governor, Eastern PA**

Paul N. Casale, MD, FACC

Dear Dr. Fischer:

Thank you for your letter of September 27, 2010. We are writing on behalf of the American College of Cardiology, the American Society of Nuclear Cardiology, and the Pennsylvania Medical Society. We are in agreement that nuclear cardiology myocardial perfusion studies should only be performed when the results of the test are likely to benefit the patient in terms of their management or outcomes. We also recognize that the health care community has a moral responsibility to society to control the costs of health care, in part by assuring that any diagnostic testing that is done is done for appropriate indications and with high standards of quality. As you know, the American College of Cardiology and the American Society of Nuclear Cardiology have for decades been leaders in setting quality standards through their extensive programs in education, through their authoritative practice, laboratory and training guidelines, and more recently through their published Appropriate Use Criteria for the various cardiac imaging modalities.

Health care insurers have every right to insist that any tests performed are done for an appropriate indication. Our task force would actively support efforts intended to reduce or eliminate unnecessary cardiac testing, including nuclear cardiology procedures, as long as that process is done properly. The process should carefully adhere to national guidelines and Appropriate Use Criteria, since those documents are the most authoritative, objective and independent standards that exist. The process should be transparent and accountable. The process must protect patient accessibility to appropriate testing. Finally, the process cannot interfere with the physician's sole responsibility to make management decisions on behalf of their patients, using their best professional judgment, as long as those decisions are consistent with national standards. **The precertification program for cardiac radionuclide studies introduced by Highmark and National Imaging Associates does not meet any of these basic quality standards.**

November 2, 2010

Donald Fischer, MD

Page 1

## Use of ACC /ASNC Appropriate Use Criteria

The assertion that the NIA guidelines and algorithms for precertification of cardiac radionuclide studies are consistent with ACC/ASNC Appropriate Use Criteria, as published in 2009, is factually incorrect and is a misrepresentation of the process. In his presentation to our Task Force and as reiterated in subsequent conversations, Dr. David Hodges described the process through which NIA developed their criteria for approving or denying nuclear cardiology studies. He indicated that they extracted information from the published Appropriate Use Criteria for Radionuclide Imaging. They then also extracted information from the Appropriate Use Criteria for Echocardiography. From those selectively extracted lists, they then developed their own separate list of criteria, based upon their selective interpretations of these published criteria, as well as their own opinions on appropriate testing. The decision algorithm as published on the NIA website and as presented by Dr. Hodges in his presentation (Guideline CG\_024, October 6, 2009, last revised 4/26/2010), does not come close to accurately reflecting the ACC/ASNC Appropriate Use Criteria for Radionuclide Imaging.

Specifically, the Appropriate Use Criteria define 33 clinical scenarios in which experts agree that radionuclide imaging studies are clearly appropriate, as supported by published peer-reviewed evidence (appropriate use criteria 7-9.) Of these 33 indications, 26 (79%) of them do not meet criteria as being acceptable indications for radionuclide studies according to the NIA algorithm (indications 2, 3, 4, 5, 6, 7, 8, 9, 11, 15, 16, 18, 19, 21, 22, 32, 35, 36, 50, 52, 55, 56, 58 (+/-), 62, 63 (+/-), 64.) **To have credibility, the decision making process for precertification of nuclear cardiology studies should be based directly upon the ACC/ASNC Appropriate Use Criteria**, because they are the best evidence-based, authoritative and objective standards that exist. The precertification process cannot be based upon some arbitrary, selective and undisclosed abstraction, compilation and reinterpretation of those criteria as has been done by NIA. Such abstraction introduces arbitrary opinion that is not evidence based, and through its generalities is subject to variability and subjective bias on the part of the reviewers, which undermines the credibility of the program.

In addition, in meetings and press releases, both Highmark and NIA have repeatedly grouped clinical indications that fall in to the uncertain category according to the Appropriate Use Criteria (appropriate use score 4-6) as being potentially inappropriate indications for a radionuclide study (category 1-3.) **We strenuously object to this position, which is a distortion and misuse of the Appropriate Use Criteria. The Appropriate Use Criteria specifically state: “The designation of “uncertain” is assumed to NOT provide grounds for denial of reimbursement.”** (JACC 2009; 53, page 2205.) If national experts in non-invasive imaging do not find criteria in published peer reviewed literature to categorize indications that fell in to the uncertain category (categories 4-6) as being inappropriate (categories 1-3), by what criteria and by what authority will Highmark and NIA determine those studies as being inappropriate? In the absence of published evidence, this can only be done by NIA physicians making arbitrary decisions based upon their own opinions as to what testing should be done in the evaluation of these patients whom they have never seen, superseding the judgment of the patient’s physician. Furthermore, if the number of “inappropriate” studies performed is as high as Highmark and NIA claim, what could be the justification in attempting to also deny studies in the AUC “uncertain” category? What is Highmark’s goal in terms of total percent of nuclear cardiology studies they are trying to eliminate from the marketplace?

## Transparency and accountability

The purpose of the precertification program is to eliminate unnecessary studies that are considered to be inappropriate. This must be done in a manner that does not interfere with patient access to studies that are indicated and appropriate. Physicians and the public have a legitimate interest in the process being completely transparent and having reasonable accountability to assure them that indicated studies are not being denied or delayed. As designed, the current precertification process lacks transparency, since it is based upon criteria developed independently by NIA, which have not been fully disclosed, and which rely heavily on subjective opinions from their cardiologists, who have never seen the patient. Is there going to be disclosure as to what percent of studies are being denied, and by what criteria? Will independent auditors be able to review denied cases, in a HIPPA compliant fashion, in order to provide verification that appropriate studies are not being denied?

## Patient Access to Studies

The precertification process must guarantee patients access to appropriately indicated studies without delay, and without subjective interference that is not based upon national standards. Denial of any patient studies that are not in ACC/ASNC appropriate use criteria categories 1-3 represents an unwarranted restriction of a patient's access to a diagnostic study that their physician believed was necessary. The American College of Cardiology, the American Society of Nuclear Cardiology, and the Pennsylvania Medical Society all strongly believe that any denial of patient access to studies in ACC/ASNC Appropriate Use Criteria indications 4-9 represents the practice of medicine without a license by an insurance company, and cannot be justified nor tolerated.

## Test Substitution

Both Highmark and NIA have repeatedly asserted that they believe stress radionuclide studies and stress echocardiograms to be comparable. Highmark has also made it clear in their comments, in their press releases, and in their website that their decision not to openly mandate test substitution of the less expensive stress echocardiography test for stress radionuclide studies, as was their originally announced plan, was based solely upon their concerns about the availability of sufficient capacity to do the volume of stress echocardiography that would result, capacity which Highmark had not considered before announcing their program.

**However, there is no factual basis in evidence based, peer-reviewed literature to support Highmark's assertion that the two tests are comparable.** There are no reported comparative trials of the two modalities published in the literature. The single published meta analysis, cited in Highmark's justification for the originally announced substitution policy (Metz LD, JACC 2007;49:227), presented extremely weak science for all the reasons that were reviewed in detail in the July 18<sup>th</sup> meeting of our Task Force with Highmark and NIA. The authors of the meta analysis were only able to identify a total of 4 published peer reviewed studies in the 15 years of published literature they reviewed that met their criteria for inclusion in the analysis; they rated 3 of those 4 as being either fair or poor in quality. Those 4 studies included only a total of 380 patients for whom there was any follow up data with respect to outcomes of myocardial infarction or unstable coronary syndromes. Follow up data on less than 400 patients would not meet even the most minimal standards for establishing the predictive power of the modality to risk stratify patients with respect to these critical outcomes, let alone establish comparability with

an alternative modality. In contrast, the published research base demonstrating the prognostic power of a radionuclide study to stratify patient outcomes is considerably more robust. Our position that the two studies are not considered to be comparable is not only supported by the literature, it is also supported by practice patterns across the country that, according to Highmark's own data as presented to our Task Force, demonstrate that the large majority of physicians across the country, including those with no financial interest in which test is performed, favor stress radionuclide studies as the preferable test compared to stress echocardiography by a ratio of approximately 3-4:1.

Highmark's assertion that the preauthorization program for radionuclide imaging does not involve mandatory test substitution is factually incorrect and misrepresents the reality of the program. Dr. David Hodges repeatedly described NIA's process for developing their criteria for when they consider radionuclide studies to be appropriate. He specifically and repeatedly stated that in developing those criteria, NIA abstracted the Appropriate Use Criteria for both stress radionuclide studies and for stress echocardiography studies. From those, they then made a determination that in their judgment "some studies will go in the radionuclide bucket, some studies will go in the stress echocardiography bucket, and some are in another bucket." We have already addressed our concerns with respect to the adjudication of the substantial percentage of studies that appear to fall in the "other bucket." However, **it is clear that NIA's criteria for when radionuclide studies are appropriate are predicated upon their opinion as to when stress echocardiograms are preferable.** Hence, even if the NIA reviewer does not specifically recommend a stress echocardiogram, if they deny the radionuclide study based upon NIA's undisclosed criteria for when they believe stress echocardiograms are preferred or comparable, that denial of the nuclear study de-facto represents test substitution to the less expensive test because the denial is based upon Highmark and NIA's opinion as to the indications for stress echocardiography.

In addition, the policy of requiring precertification for radionuclide studies while only requiring pre-notification for stress echocardiograms also encourages test substitution of stress echocardiograms for stress radionuclide studies by creating a path of least resistance, an obvious effort to encourage the market toward the lower cost, less validated test. Contrary to what was implied in your letter, not having precertification of stress echocardiograms was not done out of deference to provider concerns; it was never part of the announced Highmark program, again consistent with the intention of test substitution.

Highmark, or any insurance company, has every right to require that a test that is ordered has an approved indication. However, if two different tests both meet criteria as being appropriate tests for a given patient circumstance, it is the sole and exclusive right of the physician, together with the patient, to make the determination as to which test is preferred, based upon the patient's condition and preferences, the quality and availability of imaging resources in their community, and the physician's judgment as to which test is preferable. **Insurance companies, nor the RBMs whom they employ, do not have the right to practice medicine, and cannot either directly or indirectly mandate test substitution.** The American College of Cardiology, the American Society of Nuclear Cardiology, and the American Medical Association have all taken a strong position that mandatory test substitution by an insurance company, whether it is explicit or implicit, exceeds their authority and cannot be permitted.

### Attempted Good Faith Collaboration

Not long ago, Dr. David Hodges contacted Dr. Follansbee and asked to have a meeting. They met for a scheduled two hour meeting, and agreed to focus not on areas of disagreement but instead on the considerable areas where there is agreement. Dr. Hodges indicated that his purpose in requesting the meeting was to develop an active collaboration with our Task Force, and through us potentially with ACC, with the goal of together developing innovative, cooperative new approaches to the process of precertification of testing which could be developed in Pennsylvania and then taken across the country to other states where NIA has similar contracts. He indicated that he wanted to greatly simplify the precertification procedure, which would increase efficiency and reduce costs for both providers as well as for NIA and the insurance companies whom they represent. He discussed an initial proposal as to how this might be done. We agreed not to disclose those details. Through this proposed approach, Dr. Hodges felt that NIA could substantially reduce the number of phone calls that are necessary in the precertification process, and as a result could considerably reduce the staff of nurses and physicians that they are required to employ, thus reducing their costs. Similarly, a simplified precertification process could significantly reduce the administrative burden on physician offices. He felt that this could be accomplished while still effectively eliminating inappropriate tests. The two hour meeting became a five hour brainstorming session. Dr. Hodges cancelled his flight, Dr. Follansbee cancelled other commitments, and they continued the dialogue in a good faith collaborative effort. The proposed model evolved considerably during the ensuing discussion to a model for precertification that was based upon the 2009 ACC/ASNC Appropriate Use Criteria. The meeting could not possibly have been more collegial. Dr. Hodges agreed to present the outline for this concept to Highmark as well as to his superiors at NIA. After all the optimism and the genuine collaborative spirit that was developed in that meeting, it was deeply disappointing to discover from follow up phone calls, emails, as well as your letter, that it was all for naught. Dr. Hodges subsequently indicated that as a customer of Highmark, he could not advocate for a change in existing methodology; this was a complete reversal from the discussion and his position at the meeting. He indicated that the initiative for change would instead have to come from our Task Force. As a result, we do not see the serious quality deficiencies in NIA's programs as being solvable.

### A Far Better Solution

We would again emphasize that we agree that there is a societal need to reign in unnecessary medical imaging studies and their associated costs, including cardiac radionuclide studies. As evidenced by the above described meeting, given an appropriate opportunity to collaborate meaningfully, we will not only work with you, we will actively support you in this undertaking as long as it adheres to appropriate quality standards. We believe that the current Highmark / NIA initiative, and indeed the entire RBM model, is fatally flawed in its methodology and while it might (or might not) allow Highmark to meet its financial goals, it certainly does not protect the interests of the patients whom we all serve.

We appreciate your expressed interest in the ACC FOCUS product, which we have repeatedly proposed as being a far superior solution to achieve these goals. We have updated documentation, new since you saw a demonstration of the product, which shows that the program is now mature and quite robust, not just as an educational tool but as a precertification tool. It will be ready for deployment by December, 2010. Its advantages compared to the RBM

model are legion. As an accurate implementation of the ACC/ASNC Appropriate Use Criteria it is authoritative, independent, evidence based, transparent, objective and accountable. It has sophisticated education as well as performance monitoring capabilities. It also now has validation data demonstrating effectiveness which we believe will be superior to what can be accomplished through the RBM model. It would reduce costs and reduce the waste of valuable administrative time and resources with the serial phone calls that are inherent in the RBM model, while also eliminating the serious quality deficiencies that are inherent and unavoidable in the NIA program.

We believe that for many reasons we in Pennsylvania have a unique opportunity to establish a new, high quality model for the rest of the country to follow. We would welcome the opportunity to work collaboratively with you in that effort, and hope that you will give serious consideration to the possibility of what could be accomplished if we joined together to implement the FOCUS initiative.

Sincerely yours,



---

John U. Doherty, M.D., F.A.C.C., F.A.C.P., F.A.H.A.  
President, Pennsylvania Chapter, American College of Cardiology  
Governor, Eastern Pennsylvania



---

William P. Follansbee, M.D., F.A.C.C., F.A.C.P., F.A.S.N.C., F.A.H.A.  
Past-President, Pennsylvania Chapter, American College of Cardiology  
Chairman, PA ACC/ASNC/PA Medical Society Task Force on Cardiac Imaging  
Founding Member, American Society Nuclear Cardiology



---

Rene Alvarez, Jr. M.D., F.A.C.C., F.A.H.A.  
Governor, Western Pennsylvania Chapter, American College of Cardiology  
Vice President, Pennsylvania Chapter, American College of Cardiology



---

William Van Decker, MD, F.A.C.C., F.A.S.N.C., F.A.H.A.  
Board of Directors and Past President, American Society of Nuclear Cardiology



---

Ralph Schmeltz, M.D., F.A.C.P.  
President, Pennsylvania Medical Society

CC: Jack Lewin, CEO American College of Cardiology  
David Hodges, MD, National Imaging Associates  
James Fasules, MD, American College of Cardiology