SNMMI Value Initiative
SOCIETY OF NUCLEAR MEDICINE & MOLECULAR IMAGING

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VALUE INITIATIVE

Value Initiative 2.0 Strategic Vision

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UNIVERSITY OF UTAH

In 2018, SNMMI created the Value Initiative and Industry Alliance to advance nuclear medicine and molecular imaging. The strategic vision includes collaboration with industry, sister societies, our membership and others to showcase the crucial role of nuclear medicine and molecular imaging to the medical community, regulators, patients, and the public.

While our strategy and goals in R&D, Quality of Practice, Advocacy, Outreach and Workforce Pipeline are long-term, we have achieved key milestones in a short timeframe.

A small sample of these accomplishments in 2018-2019:

- **Quality of Practice:** Achieved **36 measurable outcomes**, including completing three AUC: prostate cancer imaging, gastrointestinal transit scintigraphy, and evaluation and treatment of differentiated thyroid cancer, all of which have been submitted to JNM.
- **Outreach:** Achieved **20 key benchmarks**, advancing patients' and the medical community's understanding of the value of nuclear medicine, molecular imaging and radionuclide therapy. Examples include holding a Patient

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Domestic Radioisotope Supply – Driving Solutions for Patient Healthcare Through Innovation, Collaboration and Shared Commitment

STEVE MERRICK, PRESIDENT AND CEO,
NORTHSTAR MEDICAL RADIOISOTOPES

When industry, academia, the U.S. government and scientific and professional societies share a common vision to address a medical supply need, the results can benefit patient healthcare. Such was the case in securing a reliable domestic supply of molybdenum-99 (Mo-99), the parent isotope of technetium-99m (Tc-99m), for the United States. Tc-99m is the most widely used imaging radioisotope. When used in conjunction with FDA-approved cold kits, Tc-99m is used to help diagnose and stage serious medical conditions such as heart disease, cancer, infection and inflammation. Tc-99m radiopharmaceuticals represent the standard of care for cardiac imaging, which represents approximately 55-60% of the 40,000 Tc-99m imaging procedures performed daily in the United States.

For decades prior to 2018, the United States was dependent on importing Mo-99 produced using highly enriched uranium. In light of frequent and sometimes prolonged Mo-99 supply interruptions impacting the availability of Tc-99m for U.S. patients' imaging procedures, and out of national security concerns about the use of highly enriched uranium in producing Mo-99, the U.S. government, industry and scientific and professional organizations took action. Legislation was enacted, technology development incentives were implemented and companies sought solutions. One company, NorthStar Medical Radioisotopes, a global innovator in the production and distribution of radioisotopes used for medical imaging, recognized the challenges faced by nuclear medicine in obtaining secure and reliable radioisotope supply, and worked to develop commercial applications in partnership with other organizations.

The first success of collaborative efforts to establish U.S. Mo-99 production to help minimize reliance on highly enriched uranium-based supply came when the FDA approved NorthStar's novel technology, the RadioGenix® System, which elutes Tc-99m from domestically produced non-uranium based Mo-99 sources. As a result, U.S.-produced, non-uranium based Mo-99 is now available, helping to alleviate ongoing Tc-99m supply shortages. Radiopharmacies using NorthStar technology have had access to more than 12 months of uninterrupted Tc-99m supply[2], despite consistent supply shortages due to issues with uranium-based Mo-99 production. The RadioGenix® System is an innovative high tech radioisotope separation platform for use in producing Tc-99m from non-uranium based Mo-99[1].

Various agencies across the U.S. government played instrumental roles in the project's success, particularly the Department of Energy's National Nuclear Security Administration (DOE/NNSA). Through its cooperative agreement program, the DOE/NNSA partners with industry and brings U.S. government resources to bear in addressing issues around national security and medical isotope supply. The objective of its efforts is to establish reliable supplies of Mo-99 to meet U.S. patient needs for Tc-99m, while advancing U.S. nuclear nonproliferation policy by eliminating the use of proliferation-sensitive highly enriched uranium in medical isotope production around the world. DOE/NNSA has partnered with NorthStar and provided funding to accelerate its efforts. DOE/NNSA has also made available technical expertise and specialized facilities at the National Laboratories to advance development of the company's technology. Additionally, the FDA and Nuclear Regulatory Commission worked alongside NorthStar in providing guidance throughout the process.

Partnerships with academic institutions can be critical in developing

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- **22%** will most likely continue to use Axumin regardless of its pass-through payment status.

In 2019, the Medicare Diagnostic Radiopharmaceutical Payment Equity Act (H.R. 3772) was introduced in the U.S. House of Representatives to preserve Medicare beneficiary access for certain diagnostic radiopharmaceuticals under the Medicare hospital outpatient prospective payment system. Our industry is dedicated to supporting patient access to innovative nuclear medicine products today and in the future. Therefore, we urge you to reach out to your members of Congress in support of H.R. 3772.

Members of Congress are particularly interested in hearing about your personal experience and how the loss of pass-through will impact you and your patients rather than simply receiving numerous pre-written letters. You can email your members of Congress directly, or you can edit the suggested letter(s) linked here before submitting.

- www.rightscanrighttime.org/act_pet
- www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=32244

Axumin® (fluciclovine F18) Injection Indication

Axumin injection is indicated for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment.

Axumin® (fluciclovine F18) Injection Important Safety Information

- Image interpretation errors can occur with Axumin PET imaging. A negative image does not rule out recurrent prostate cancer and a positive image does not confirm its presence. The performance of Axumin seems to be affected by PSA levels. Axumin uptake may occur with other cancers and benign prostatic hypertrophy in primary prostate cancer. Clinical correlation, which may include examination of tissue samples, is recommended.
- Severe allergic reactions, including anaphylaxis, may occur in patients who receive Axumin. Emergency resuscitation equipment and personnel should be immediately available.
- Axumin use contributes to a patient's overall long-term cumulative radiation exposure, which is associated with an increased risk of cancer. Safe handling practices should be used to minimize radiation exposure to the patient and health care providers.
- Adverse reactions were reported in ≤1% of subjects during clinical studies with Axumin. The most common adverse reactions were redness and pain at the injection site, and an unusual taste in the mouth.

To report suspected adverse reactions to Axumin, call **1-855-AXUMIN1** (1-855-298-6461) or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Full Axumin prescribing information is available at: www.axumin.com.

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Guideline for Prostate Cancer(Version 2.2018). ©National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed 03/30/2018. To view the most recent and complete version of the guideline, go to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
2. Froemming AT, Verma S, Eberhardt SC, et al., for the Expert Panel on Urologic Imaging. American College of Radiology, ACR Appropriateness Criteria® (Post-treatment Follow-up of Prostate Cancer). ©2017 American College of Radiology. https://acsearch.acr.org/ docs/69369/Narrative/. Accessed 03/3/2018.
3. Andriole GL, Kostakoglu L, Chau A, et al. The impact of positron emission tomography with ^{18}F-Fluciclovine on the management of patients with biochemical recurrence of prostate cancer: results from the LOCATE trial. *J Urol*. 2018;doi:10/1016/ j.juro.2018/08.050.

* As of January 1, 2017, all local MACs confirmed that Axumin is covered for its label indication. Please check with the MAC that covers your Medicare patients to determine their specific coverage policies.

An article by Blue Earth Diagnostics, A Bracco Company, a SNMMI Value Initiative Industry Alliance Leadership Circle Partner.

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radioisotope technology. Beginning in 2009, NorthStar worked in collaboration with the University of Missouri Research Reactor (MURR®), the highest-power university research reactor in the United States. With a shared vision to alleviate radioisotope supply shortages and advance research, NorthStar and MURR refined and developed Mo-99 production technology based on stable molybdenum rather than enriched uranium. With neutron capture technology, the isotope Mo-98 is irradiated to form Mo-99. Neutron capture avoids potential national security and environmental concerns associated with enriched uranium.

Through advocacy and outreach, scientific and professional organizations such as SNMMI encouraged development of new technologies and domestic production facilities to secure reliable domestic Mo-99 supply. Educational programs and support for technology innovation help advance the role of nuclear medicine to the medical community, regulators, patients and the public.

As seen in this case of U.S. Mo-99 supply, effective collaboration combined with well-executed technology development can help advance concepts into real-world solutions to benefit patient healthcare. With FDA approval and commercial availability, NorthStar's initial technology success is translating into ongoing expansion, development of increasingly efficient radioisotope production using neutron capture and accelerator technologies and research to produce additional radioisotopes. New production technologies will enable the United States to diversify the means of Mo-99 production so that industry is no longer reliant solely on a technology with its acknowledged limitations and risks. Through the efforts of companies like NorthStar Medical Radioisotopes working in partnership with government, academic institutions and professional societies, the future for U.S. radioisotope supply to meet patient and research needs appears dynamic and promising.

1. For Important risk information for the RadioGenix System click here. For full RadioGenix® System prescribing information, visit: https://www.northstarnm.com/wp-content/uploads/2019/08/radiogenix-system-pi-july2019.pdf.
2. Duration as of December, 2019

An article by NorthStar Medical Radioisotopes, a SNMMI Value Initiative Industry Alliance Corporate Member Partner.