F-18 Fluorodeoxyglucose—Part of Your Imaging Arsenal

By Eleanor S. Mantel, CNMT, FSNMMI-TS, and Jessica Williams, CNMT, RT(N), FSNMMI-TS

As the New Year gets underway, my focus is on professional development and education—advancing nuclear medicine technology through increased opportunities for current and new technologists.

This educational focus nicely complements our existing initiatives. Specifically, for the Quality Initiative—led by April Mann, MBA, CNMT, NCT, RT(N), SNMMI-TS is dedicated to the advancement of molecular and nuclear medicine technologists by providing education, advocating for the profession, and supporting research to achieve clinical excellence and optimal patient outcomes.

In the last edition of Uptake, you learned about carbon-11 choline (¹¹C-choline) and how, imaging-wise, it benefits patients with prostate cancer. Since ¹¹C-choline is not widely available and requires an institution to be in close proximity to a cyclotron, we are going to discuss a different option—one that some are calling one of the best imaging agents for prostate cancer—fluorine-18-labeled 1-amino-3-fluorocyclobutane-1-carboxylic acid (¹⁸F-fluciclovine). Known commercially as Axumin® and manufactured by Blue Earth, fluciclovine was FDA approved for clinical use in prostate cancer in May 2016. It is available from select commercial radiopharmacies. This synthetic amino acid is tagged with fluorine-18 and targets the increased amino acid transport that takes place in many cancers.

Prostate cancer is the second leading cause of cancer death in males in the United States. In 2016 alone, more than 180,800 cases of prostate cancer were diagnosed, according to the American Cancer Society (ACS). ACS estimates that approximately one in seven men will be diagnosed with prostate cancer in their lifetime. Relapse is a significant issue with prostate cancer, occurring in 20% to 50% of patients.¹

The current standard of care for prostate cancer includes whole-body bone scans with ⁹⁹ᵐTc-MDP and pelvic imaging with CT and MRI. For patients with suspected relapse who have already had prostatectomies, these common methods aren’t as informative as physicians would like. FDG PET/CT scans are not an ideal option for imaging for a few reasons. FDG is a radioactive glucose, and since glucose appears in urine, detection of cancer on the prostate bed is difficult due to the proximity of the bladder. FDG also generally has low uptake in prostate cancer prior to the development of castration-resistant disease. Fluorodeoxyglucose was developed by Mark Goodman, PhD, and Timothy Shoup, PhD. The method of localization is through trans-membrane amino acid transporters ASCT2 and LAT1. These two important amino acids are associated with more aggressive tumor behavior. The usefulness of fluciclovine for prostate cancer was discovered with suspected relapse who have already had prostatectomies, these common methods aren’t as informative as physicians would like. FDG PET/CT scans are not an ideal option for imaging for a few reasons. FDG is a radioactive glucose, and since glucose appears in urine, detection of cancer on the prostate bed is difficult due to the proximity of the bladder. FDG also generally has low uptake in prostate cancer prior to the development of castration-resistant disease. Fluorodeoxyglucose was developed by Mark Goodman, PhD, and Timothy Shoup, PhD. The method of localization is through trans-membrane amino acid transporters ASCT2 and LAT1. These two important amino acids are associated with more aggressive tumor behavior. The usefulness of fluciclovine for prostate cancer was discovered

Message from the President-Elect

By Kathleen M. Krisak, BS, CNMT, FSNMMI-TS

As the New Year gets underway, my focus is on professional development and education—advancing nuclear medicine technology through increased opportunities for current and new technologists.

This educational focus nicely complements our existing initiatives. Specifically, for the Quality Initiative—led by April Mann, MBA, CNMT, NCT, RT(N), FSNMMI-TS—ongoing education helps ensure safe, effective, patient-centered care. In addition, in our efforts to address infringements on scope of practice (a major focus of SNMMI-TS President Sara G. Johnson, MBA, CNMT, NCT, FSNMMI-TS), the SNMMI-TS will provide technologists with the tools needed to be leaders within the field, so they can work comfortably with other departments

Continued on page 4 see President-Elect's Message
Since the mid-2000s, the USP <797> Standard (USP 797) has been discussed and written about in nuclear medicine meetings, journals and newsletters. The flow of information has slowed over the past few years but the news is this: a new revision of this standard is due out any day and it impacts you.

In 2004, The Joint Commission (TJC) defined radiopharmaceuticals and other imaging under the supervision of the director of pharmacy. The compliance regulations are defined in TJC’s Medication Management chapter. The United States Pharmacopeial Convention (USP) is an organization that sets standards to ensure the high quality of U.S. drugs. These standards are enforceable by the U.S. Food and Drug Administration. These organizations regulate nuclear medicine radiopharmacies, along with traditional hospital and outsourced pharmacies.

All commercial radiopharmacies, as well as some hospital and outpatient hot labs that “prepare” or “compound” radiopharmaceuticals, must be licensed as compounding facilities in your state. These facilities are inspected by the State Board of Pharmacy (BOP). The BOP uses both TJC medicatin management standards and USP 797 to assure compliance. If your hot lab is licensed, your participation is essential to make sure the technologists participate in yearly training and, at a minimum, your hot lab is progressing toward USP 797 facility compliance. Additionally, departments must have a plan in place and have shown effort to move toward that goal. Even if your hot lab is not licensed and your technologists prepare radiopharmaceuticals, it is best practice for them to have ongoing training and competency testing as required in USP 797.

Furthermore, policies need to be written for your technologists that define the evaluation and time intervals of their aseptic technique testing, hand cleansing, and proper garbing and gowneding during the compounding of radiopharmaceuticals in the hot lab. You will need a policy to state how and when you will monitor the hot lab for surface microbial contamination and the time intervals for cleaning and disinfecting it. Those are the easiest and cheapest compliance tests.

The next set of standards will cost money to comply. Technologists will need to be evaluated through observation and testing of fingertip sampling and media fill challenges. Chances are that your hospital pharmacy has a policy in place for these and can implement the tests for technologists. Otherwise, ask your nuclear pharmacy for assistance and see what is available. Make a spreadsheet of what tests are due and when.

If the BOP, TJC or Department of Health surveys your department and you are asked by surveyors about your plan for USP 797 compliance, show them the spreadsheet detailing when your technologist competencies are performed, when the cleaning is performed, how often your media fill challenges and fingertip testing are performed, and your policy numbers as references. As for USP 797 environmental testing in the hot lab, have a timeline ready to present for a gap analysis performance.

Some institutional radiopharmacies have difficulty meeting the facility requirements of USP 797, such as a clean room. Most BOPs are reasonable, and if you show them your facility’s construction schedule when Your State’s Board of Pharmacy Comes Calling
Axumin and NETSPOT Are Approved—Now What?

O

ver the last 20 years, U.S. Food and Drug Administration (FDA) approvals of new radiopharmaceuticals for positron emission tomography (PET) have been sparse. Fortunately, this past spring, two radioactive diagnostic agents indicated for PET—

$^{18}$F-fluciclovine (Axumin®) and $^{68}$Ga-DOTATATE (NETSPOT®)—were approved by the FDA. Suddenly, the race is on to get these novel imaging agents to patients in need. Axumin is indicated for men with suspected prostate cancer recurrence. NETSPOT will help locate tumors in adult and pediatric patients with somatostatin receptor-positive neuroendocrine tumors (NETs). With the approval of these two agents, hospital and imaging center administrators are forced to get creative in bringing these imaging exams to their facilities and to their patients.

So, why is it complicated? For one, these drugs are expensive. The price for both drugs is in the range of $3,000 to $4,000 per dose. Payment is another concern. The Centers for Medicare & Medicaid Services (CMS) will cover PET with these agents for the FDA-labeled indications under the current provisions in the national coverage policy for new oncologic PET radiopharmaceuticals. CMS also has assigned drug codes and has approved pass-through on these agents effective January 1, 2017. However, most commercial payers have not yet clearly made coverage determination or, worse yet, have already declared these agents as investigational, despite FDA approval. PET center logistics also need to be considered and addressed to properly bring these drugs into practice.

How do you deal with the sticker shock of these newly approved PET agents? First, you must realize that, in essence, PET with Axumin will be replacing planar and SPECT imaging with $^{111}$In-capromab pendetide (Prostascint®), and PET with NETSPOT will be taking the place of $^{111}$In-pentetreotide (Octreoscan®). All four agents have similar price tags, but one major difference exists in the way that CMS will reimburse for these drugs for Medicare patients. Currently, Medicare is packaging the payment of Prostascint and Octreoscan into the Ambulatory Payment Classification (APC). This payment mechanism combines the CPT (exam code) and HCPCS (drug code) into one payment, which usually results in the inability to recover the full cost of the drug. However, CMS has approved pass-through for Axumin and NETSPOT, thus putting the imaging centers in a position where they can recover all drug costs (at least for a while—pass-through status lasts for no longer than three years).

What about commercial payers? Acquiring insurance preauthorization for general PET/CT exams (CPT codes 78815 or 78816) is not particularly difficult; however, getting commercial payers to preauthorize the actual radiopharmaceutical is a challenge. What we are seeing is that insurance companies will preauthorize the PET exam or state that the CPT code does not need authorization—but will not commit to authorize the radiopharmaceutical.

The risk of not receiving preauthorization and coverage for $^{18}$F-FDG is not dire, as the per-dose cost is approximately $125. With the new agents, there is much greater financial risk. In consideration of financial risk, you can improve your chances of getting the new agents reimbursed by encouraging your referring physician teams to be very clear with payers about the cost of the drug that goes with the CPT code. The goal is for the insurance companies to understand the actual cost of the studies they are preauthorizing. We also encourage referring physicians to directly seek approval for the specific imaging exams and radiopharmaceuticals by starting peer-to-peer discussions with insurance companies. Once the examination has been billed, it is essential to follow up and to perform retroactive audits on reimbursement results from your commercial payer claims. Report denial information to the appropriate drug vendors so they can continue their work with insurance companies. Also, assist patients and referring physicians with supportive information to handle denied claims. Use the SNMMI Coding Corner, Coding & Reimbursement Q&A section on the SNMMI website—a nice perk for SNMMI members—for specific and updated guidelines on how to code these two exams.

Now that you have payment figured out, how do you fit these new studies into your busy PET schedule? One thing to keep in mind is that both Axumin and NETSPOT are new to the market and are slowly being eased in to match demand; thus their availability at this point is limited both on days and markets. Your current oncologic, brain, and bone PET scheduling matrix will need to be adjusted to open slots during the limited times these new drugs are available at your facility. The imaging protocols are also different than what we are generally accustomed to with most conventional PET studies. Specifically, Axumin requires injection while the patient is in position on the scanner bed, since imaging must begin within five minutes of injection. The NETSPOT uptake procedure is similar to that for $^{18}$F-FDG, but imaging time is longer. To take on the new demand, study these new protocols, understand how to make them fit into your current schedule, and then be creative in keeping accessibility open for traditional PET exams while adding slots.

Bringing Axumin and NETSPOT to your PET imaging facility will not be easy. It will require commitment, creativity and appropriate negotiation, but its success will result in improved overall patient care and growth in PET volume.
The mile-high city—Denver, Colorado—is situated in close proximity to the beautiful Rocky Mountains. The June weather gives visitors the ability to experience all that this capital city has to offer. The nearby mountains and the numerous national and state parks will appeal to adventurous individuals. For those who feel less adventurous, there are more than enough museums and restaurants to visit. These activities and the opportunity to receive continuing education credits is a great reason for you to join us for the 2017 Annual Meeting on June 10-14.

The Technologist Program Committee has assembled a continuing education program to meet everyone's needs and interests. The continuing education sessions are scheduled to begin on Saturday, June 10. There are two full-day sessions, one focusing on gastrointestinal imaging and the other focusing on management and leadership. General technologist and physician continuing education sessions begin Saturday afternoon and continue through Wednesday. Utilize the meeting grid and online planner to identify which sessions you will be attending.

When you are not in sessions or taking in the entertainment or dining options of Denver, network with national and international friends and colleagues. There are many opportunities for networking at the meeting, including the Hot Trot and Welcome Reception on Saturday, the party on Tuesday and the numerous coffee breaks in the exhibit hall throughout the meeting. Be sure to visit the exhibit hall and meet with the vendors that help to make this meeting possible. Stroll through the abstract poster hall. Many of your colleagues have put time and effort into submitting abstracts and posters—take some time to show them your support.

Check the website frequently for additional information and meeting updates. Start making your plans to attend the meeting in Denver! We look forward to seeing you there.
Deborah Gibbs first became interested in nuclear medicine during her senior year of high school, when she worked handling specimens as a pathology processor. This put her in touch with pathologists—physicians usually reading nuclear medicine studies at that time. The nuclear medicine department happened to be across the hall from her lab, and she found the procedures fascinating—so much so that three pathologists recommended her for enrollment in the local program at the Medical College of Georgia (now Augusta University).

At 17 years of age, however, adverse life circumstances made her responsible for her own support, so she had to work “non-stop” at multiple simultaneous jobs and attend courses through the summers. “I was always teased for ‘working too much,’” she recalls. Often she made barely enough money for meals and books. Deborah feels that this difficult period was instrumental in the development of her character. Her diligence resulted in a Bachelor of Radiological Sciences degree in 1991. Since then, she has used the discipline she acquired at that early age to produce an exemplary career.

Deborah has worked in a variety of settings and obtained nuclear cardiology, PET and CT specialty certifications as well as cross-training in ultrasound. She has managed a cardiology imaging lab and served as a clinical coordinator for a nuclear medicine educational program. For 13 years Deborah was the nuclear medicine lead and cancer clinical trials administrator at the University of Augusta, gaining a Collaborative Institutional Training Initiative (CITI) certification. In 2008 she received her Master of Education degree from Southern Wesleyan University, and in 2014 she earned a radiation safety officer certification. Deborah presently is a radiology chief at Augusta’s Veterans Health Administration Charlie Norwood Medical Center, overseeing nuclear medicine, PET/CT, MRI and CT, as well as general and vascular ultrasound.

The nuclear medicine field has given Deborah rewarding and meaningful experiences. Involvement with collaborative patient management projects enriches her job. In this capacity she works with passionate technologists to find new procedures and services to positively affect patient outcomes. She admires the sense of professionalism she encounters when networking with technologists, physicians and physicists. She cites “the opportunities to grow, share, and lift others” as among her favorite aspects of nuclear medicine, and adds, “this makes my choice a career and not just a job.” She has earned a Sigma Green Belt from the American Society for Quality, applying her management skills in reviewing processes to improve efficiency and patient results. She finds gratification in this, explaining, “Management offers an opportunity to create real, positive change in a sometimes challenging environment.”

She acknowledges that the environment can indeed sometimes be challenging. She remembers a period in which she had been on call continuously for two weeks, and after many call-ins, she again was paged at 1:30 a.m. “I literally just broke down and cried as I changed into my scrubs and grabbed my car keys and left for the hospital,” she admits. She adds, “I kept reminding myself that ‘this too shall pass.’”

Among administrative environmental challenges, Deborah has found that productivity expectations do not take into account the physiological processes on which nuclear medicine procedures depend. “No matter how you slice it, the radiopharmaceutical will not localize any faster than the molecules can metabolize them,” she explained.

Since 1991, Deborah has been active in the SNMMI-TS. She is also a member of the Augusta Nuclear Technologists Society (ANTS), the Georgia Society of Nuclear Medicine Technologists (GSNMT) and the Southeastern Chapter (SEC). She has served as president of the GSNMT and the SEC TS chapter. In becoming involved with the society, her mentors include George Yoder, Mary Ann (Mimi) Owen, and Danny Basso (among many others). She has been active in committee work for her chapter as well as for the SNMMI-TS, including the Finance and Membership committees as well as the Clinical Trials Network (CTN). She is most proud of her role in developing the CTN webinar, Quality Control Standards in Clinical Trials. Additionally, she has contributed to the Journal of Nuclear Medicine Technology and has served as an item-writer for the Nuclear Medicine Technology Certification Board.

Deborah has found that being involved with the SNMMI-TS on a national level has expanded her knowledge base of practices, which she can share with others. She adds, “It is also an honor to participate in discussions and decisions that have a real impact on our profession.”

Even with all her achievements, Deborah and her husband of 27 years raised two boys, who are now attending college. They are adjusting to their “empty-nester” identity by spending time with their two dogs, watching movies, cooking, kayaking and traveling. In addition to the rewards of family life, Deborah was greatly honored and humbled when in 2016 her colleagues recognized her as a Fellow—something she values as the highest honor in the profession.

When asked to identify a cause in the profession she feels most passionate about, Deborah remarked that some health care providers do not realize the absolute importance of their work. To pass on the right approach, she stresses the importance of being a good role model for student technologists. She adds, “Educating people and sharing the passion of going above and beyond is the key.”
As we begin 2017, one of the many projects technologists may be facing is the renewal of a national or state certification and/or license. In preparing the required documentation for renewal, technologists will need to provide the regulatory agency or certifying organization with proof of attendance for educational programs to meet the minimum criteria for renewal—either up front or in response to an audit. As an SNMMI-TS member benefit, VOICE transcripts provide you with a concise summary of attended programs, and those transcripts are readily accepted by most regulatory agencies. For those technologists that have opted to have educational credits automatically forwarded to the ARRT or NMTCB, the only steps needed to complete the renewal process will be to pay the necessary renewal fee and to answer the required ethics questions.

But what happens when you review your VOICE transcript and credits are missing—or, worst case scenario, you forgot to review your transcript before your renewal date and you are contacted by the ARRT or NMTCB with a notification that your credits fall short of the required minimum for renewal? You know that you attended the required number of programs, you have your cancelled checks or credit card receipts, but the credits are not displayed—and without those credits, you cannot complete your renewal process.

In most cases, the answer to that question is a simple one. You most likely missed that important final step needed to accurately record your educational credits: the online evaluation of the educational program. During that process, you evaluate the program and the speakers, and at the conclusion of the evaluation process, your credits are added to your VOICE transcript. Then you have the opportunity to print a hard copy of your VOICE certificate for your own personal records.

So, what do you need to do if you don’t remember receiving the email from the SNMMI with instructions for that process? As a member of the SNMMI, if you gave the sponsor of the educational program the same email address that is on file with the SNMMI, you can quickly review and complete the required evaluation as follows:

- Log into the SNMMI website at www.snmmi.org
- Click on ‘Education’
- Click on ‘My Activities’
  - Select the missing program
  - Follow the instructions to complete the required program evaluation
  - Print your VOICE certificate
  - Review and print, as necessary, your revised VOICE transcript

But what if you don’t see the program that you attended listed under ‘My Activities’? In that case, contact the sponsor of the educational program for assistance. Working with the educational sponsor and the SNMMI’s Education Department, your attendance can be quickly verified and the program added to “My Activities.” Complete the necessary evaluation process, and the credits will be added to your VOICE transcript.

**Important note:** The opportunity to add CE credits approved by an ARRT-RCEEM provider to your VOICE transcript has been a valuable member benefit for many years (see ‘Add My Own Activity’ on your ‘My transcript’ link at www.snmmilearningcenter.org). Adding ARRT-RCEEM–approved educational credits to your VOICE transcript allows you to have a complete summary of your educational activities; however, please remember that only those programs that have been approved by the SNMMI will be transmitted to the ARRT or NMTCB. CE credits acquired from other ARRT-RCEEM–approved educational programs must be added to your renewal application and forwarded to the appropriate certifying organization or regulatory agency.

If you have any questions or need additional information, please contact me at ksthomas0412@msn.com or contact Caroline Krystek at ckrystek@snmmi.org.
quite by accident. In early research, fluciclovine was being tested for imaging brain tumors. Approximately 10 years ago, researchers at Emory realized that fluciclovine had minimal urine uptake and were testing imaging on a patient with renal cancer. This is when they discovered that prostate cancer is an excellent candidate for imaging with fluciclovine. Biodistribution normally has high uptake in the liver and pancreas, mild uptake in the salivary and pituitary glands and muscle, and mild to no uptake in brain and lungs. The bladder can show immediately, with low to mild uptake that can increase over time.

Currently imaging is approved for patients with history of prostate cancer and suspected recurrence based on elevated prostate-specific antigen (PSA). Patient prep includes nothing by mouth for 4 or more hours prior to imaging. Patients should also avoid exercising the day before. They should empty their bladder prior to being set up on the scanner. Ten millicuries of fluciclovine is injected into the right arm, ideally, while the patient is on the scanner. Right arm injection is to avoid misinterpretation of visualization (not due to tumor uptake) of lymph nodes in the left axilla known as “Virchow’s node.” Imaging begins 4 minutes after injection and the patient is imaged from mid-thigh to the base of the skull. The suggested guideline is 5 minutes per bed over the pelvis and 3 minutes per bed over the rest of the body; this may be modified depending on imaging acquisition equipment being utilized.

Even though fluciclovine has already been FDA-approved, ongoing research in breast cancer and brain tumors may expand its utility. Adding fluciclovine to the imaging arsenal for prostate cancer will aid in earlier detection of recurrence. Early detection can result in better outcomes and fewer side effects that can negatively impact a patient’s quality of life.

Your “My SNMMI” dashboard is an easy way to navigate the numerous member benefits available to you. It helps you keep track of activities and allows you to easily update communication preferences throughout your membership. We encourage you to bookmark this page for future use.

Here’s how to get there:
2. Click on “Log In” at the upper right-hand corner of the page, and type in your Username and Password. (If you don’t remember them, call Member Services for help, or email memberinfo@snmmi.org)
3. Again at the upper right-hand corner, click on “My SNMMI.” This is where you’ll find your member dashboard.

Once you’ve logged in, you can now customize your member experience by adjusting your SNMMI profile options. For example:
• Manage your email and publication preferences to customize which news you receive from SNMMI (My Preferences tab)
• Choose/Update your journal preferences. Membership includes online access to The Journal of Nuclear Medicine and the Journal of Nuclear Medicine Technology. If you want to receive print issues as well, you can sign up for that here (My Preferences tab, Publications Preferences)
• Review your credit history, see your transcript, and access the SNMMI Learning Center (My SNMMI tab)
• List professional information including degrees, certifications, and areas of practice. (My Profile tab, Professional Information)
• Update your contact information. Stay up-to-date with the latest news from the Society by updating your email and mailing address as needed (My Profile tab)
• Access the SNMMI Member Directory and expand your professional network (My SNMMI tab)

SNMMI wants you to have the best possible member experience. If we can help you, let us know. Email us at memberinfo@snmmi.org, or call 703-708-9000.

---

Customize Your Online SNMMI Experience
Make sure you are getting the most from your membership!

---

Reaching New Heights in the Mile High City!
RACE REGISTRATION IS NOW OPEN!

Saturdays, June 10, 2017 • Denver, CO

Individual and Teams Are Welcome! Sign Up Today!
www.snmmi.org/HotTrot5K

NEW THIS YEAR
Virtual option!

Can’t make it to Denver but really want the medal? Sign up today! Your swag bag and medal will be mailed after June 10, 2017.
indicating that a remodel is in progress, they will issue a waiver for the radiopharmacy itself.

A new revision of the USP 797 is due to be released any day pending approval from USP experts. The proposed revision reduces the three categories of risk down to two, depending partly on the expiration date—also called the Beyond Use Date (BUD). Red blood cell labeling is not specifically mentioned. The proposed language also states, “Unless done in strict conformance with the manufacturer’s package insert, any further use or handling and manipulation of conventionally manufactured radiopharmaceutical product is considered compounding and must follow the standards in this chapter and applicable federal, state, and local laws and regulations.” Once the final USP 797 language is out, it will be posted on the SNMMI website.

Should you need assistance with sample policies or other information, please contact hpra@snmmi.org.