New PET Scan Approved for Prostate Cancer – for PSA Recurrence After Treatment

On May 27, 2016, the FDA approved a new PET Scan tracer (injection) for prostate cancer patients with “suspected prostate cancer recurrence based on elevated prostate specific antigen (PSA) levels following prior treatment.” (1) There are several names for this new PET imaging agent, but they are the same agent:

- **Axumin** (brand name)
- **fluciclovine** (generic name)
- **FACBC** (previous clinical trial name)

A PET Scan is a type of medical imaging trying to locate your cancer—especially outside the prostate.
It should probably be noted that this new PET Scan tracer was not studied in men on hormone therapy, but there are some studies that show its effectiveness in men with a rising PSA on hormone therapy, or “CRPC” (castrate resistant prostate cancer). (2) As always, ask about insurance coverage and reimbursement. But clearly this PET imaging could help fill a space where prostate cancer patients and their doctors are trying to make a treatment decision after surgery, and perhaps considering salvage radiation. It may help some men make a decision on spot radiation or surgical removal of a lymph node in the setting of a rising PSA. It may also help a patient make the decision to start hormone therapy, or other systemic treatments, instead of a more localized therapy. These are all issues to research, and discuss with your doctors, but they are some of the possible scenarios where this PET Scan may be helpful.

Two studies helped the Axumin PET Scan obtain its FDA approval. In one study, results from the Axumin PET Scans were compared with biopsy pathology, and read by several radiologists independent of each other.(1) The second study compared the Axumin PET Scan to the C11 Choline PET Scan, which is currently available at the Mayo Clinic. (3) Patients in this study had a median PSA of 1.44. (Median is the middle number, not the average number.) Again, several radiologists read the scans independently and reported their findings. Based on these 2 studies, the FDA ruled that the Axumin PET Scan was both safe and effective.

It is important to note that there are different types of PET Scans – not all are the same. The most commonly used PET Scan in cancer imaging overall is the FDG PET, which uses a glucose based tracer (injection). The FDG PET has not proven
very accurate in prostate cancer, although there are some exceptions in very aggressive or late stage disease. Currently (summer 2016), there probably 3 other PET Scans in prostate cancer that are most commonly used (with several more still in clinical trials). These include the F18 Sodium Fluoride PET Bone Scan, the C11 Choline PET at Mayo Clinic (for PC recurrence), and the C11 Acetate still in phase 2 trials. All of this is subject to change, of course.

Better questions will get you better answers. Always research a question before you ask your doctor(s).

It is also important to remember that no medical imaging is 100% perfect. They all have degrees of accuracy based on what they are looking for, what part of the body they are imaging. Always ask your physician(s) about the accuracy of a scan that you have received, whether it is PET, CT, bone scan or MRI, or anything else. This will help with your overall understanding of your disease state and treatment decisions. It is also important to note that Blue Earth has stated that “Axumin uptake may occur with other cancers”(3). So for men with another type of cancer in addition to prostate cancer, this should be discussed with the radiologist and/or nuclear medicine physician interpreting the PET Scan. A more detailed, developed understanding of the extent of accuracy (sensitivity and specificity) of Axumin PET is still being
As with all FDA approvals, a product can take a while to really be available on the market for patients. Currently, I have been told by Blue Earth Diagnostics (the manufacturer) that the PET Scan should be available in a few places in the USA by mid to late summer. To find current information about availability of the Axumin PET Scan, call 1-855-AXUMIN1 (1-855-298-6461).

However – this PET Scan is available in this clinical trial which is recruiting in Los Angeles, and planning on opening many more sites over the next year.

18F Fluciclovine (FACBC) PET/CT in Patients With Rising PSA After Initial Prostate Cancer Treatment (LOCATE)
No placebo – all patients get PET Scan

Basic Eligibility Criteria:

- Prior surgery, radiation, brachytherapy, or other local treatment for prostate cancer
- For surgery patients – at least 1 year since surgery
- For all other patients – at least 2 years since treatment
- Rising PSA which includes the following:
  - For surgery patients, a PSA of 0.2 and rising
  - For patients who had radiation or other local treatment, a PSA that has risen 2.0 or more above PSA nadir
- Off hormone therapy – for 3 months or longer
- No known metastases (previous CT and/or bone scans negative)

(For full eligibility criteria, check with contact...
At the time this article is being written (summer 2016), Blue Earth Diagnostics has stated that they hope to roll out commercial availability in mid to late summer. Although Blue Earth is the manufacturer, PETNET Solutions (a subsidiary of Siemens Medical Solutions USA) has commercial rights to manufacture, distribute, and sell Axumin in the U.S. (4)

At the time this article is being written, there is also no detailed information on Medicare or insurance coverage yet. Stay tuned to PAACT’s Facebook page for updates, or call PAACT at (844) PAACT 4U.

References
