Nuclear Regulatory Commission Public Meeting: Training and Experience Requirements for Alpha and Beta Emitter Products

CELEBRATING 30 YEARS OF HOPE

FLORIDA CANCER SPECIALISTS & Research Institute

World Class Medicine. Hometown Care.

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Clinical Benefit of Therapeutic Radiopharmaceuticals

- Less intensive treatment schedule
- Far less constitutional and somatic toxicities
- Potential for more durable responses when compared to conventional chemotherapy
- Benefits especially important for elderly cancer patients with mobility and access limitations

Clinician Role in Zevalin Treatment

Diagnoses and treats patient prior to Zevalin	Hematologist/ Medical Oncologist
Offers Zevalin as an option to patients	Hematologist/ Medical Oncologist
Routinely administers rituximab (a component of the Zevalin regimen)	Hematologist/ Medical Oncologist
Routinely handles most common and serious side effects of Zevalin	Hematologist/ Medical Oncologist
Additional training currently required to become an Authorized User to prescribe and administer Zevalin	Hematologist/ Medical Oncologist require 700 hours training & experience + 3 proctored cases
Available Authorized Users to treat Zevalin patients	Very few Hematologists/ Medical Oncologists

Dr. Joseph Mace:
Training & Experience to Administer Therapeutic Radiopharmaceuticals

- Dr. Mace gained Authorized User status before the current 700-hour training & experience requirement was put into place
- Dr. Mace completed a radiation safety and handling course that met the 80-hour requirement
  - "After my course experience, I felt fully prepared to administer Zevalin, with all of the attendant radiation safety and handling issues."
- Dr. Mace has been administering Zevalin safely for 10 years and Xofigo safely for nearly 2 years with no safety incidents
- Patients can be treated in the community oncology setting without traveling to a regional academic medical center
  - "Patients clearly appreciated the fact that it was the same physician seeing them in consultation to discuss Zevalin therapy, subsequently administering the agent, and monitoring them for the requisite 2-3 months thereafter."

Dr. Jennifer Cultrera:
Regulatory Barriers to Administering Therapeutic Radiopharmaceuticals

- Experienced with Zevalin in the academic setting but cannot realistically undertake 700 hours of training and experience
- In current community setting, need to find an AU who can provide the treatment, adversely impacting continuity of care
- Physicians discouraged from recommending treatment due to the burden regulations place on patient access

Impact on Development of Therapeutic Radiopharmaceuticals

- The training and experience requirements discourage clinicians from recommending Zevalin and other therapeutic radiopharmaceuticals
- There is a lack of exposure to therapeutic radiopharmaceuticals during hematology/medical oncology fellowships due to poor access to these agents
- Regulatory barriers have already contributed to the removal of one therapeutic radiopharmaceuticals product from the market
- More therapeutic radiopharmaceuticals are in the development and approval stages, but innovation is in danger of being stifled