Department of Veterans Affairs

Memorandum

Date:

OCT 03 2018

From: Deputy Under Secretary for Health for Operations and Management (10N)

- subj: INFORMATION BULLETIN: Appropriate Use of Proton Therapy for Radiation Therapy Treatment 2018 Update (VIEWS 00102718)
- To: Network Directors (10N1-23)
 Facility Directors (00)
 - 1. Radiation therapy using charged particles, like protons, delivers ionizing radiation with greater precision and less dose to surrounding normal tissues. Controlling the particle energy allows the beam to be stopped at a designed depth. As a result, proton therapy may be preferred when the sparing of normal tissue offers a clinical benefit, which cannot be obtained using photon irradiation.
 - 2. Examined clinically since the 1980s, proton beam therapy has potential benefits, which must be examined case-by-case. Determining both the risk of normal tissue injury and the ability to deliver a therapeutic dose to the tumor each in comparison to advanced photon therapies has frequently demonstrated an advantage for proton beam therapy in those clinical presentations listed below. These have been identified by the American Society for Radiation Oncology (ASTRO) as Group 1 indications for proton therapy. The non-pediatric indications are shown below:
 - a. Malignant and benign primary central nervous system (CNS) tumors;
 - b. Advanced (e.g., T4) and/or unresectable head and neck cancers;
 - c. Cancers of the paranasal sinuses and other accessory sinuses;
 - d. Non-metastatic retroperitoneal sarcomas;
 - e. Reirradiation cases where cumulative critical structure dose would exceed tolerance dose:
 - f. Hepatocellular cancer (no longer required to be treated in a hypofractionated regimen);
 - g. Ocular tumors, including intraocular melanomas;
 - h. Tumors that approach or are located at the base of skull, including but not

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limited to chordoma and chondrosarcomas:

- i. Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated;
- j. Patients with genetic syndromes making total volume of radiation minimization crucial, such as but not limited to NF-1 patients and retinoblastoma patients.
- 3. The appropriate examination and selection of proton therapy for a Veteran diagnosed with one of the above presentations will be decided by a Veterans Health Administration (VHA) attending radiation oncologist in collaboration with a proton therapy specialist.
- 4. Though generally not supported by current clinical evidence, proton therapy research is in progress for the broad spectrum of clinical presentations listed below as ASTRO Group 2 indications. The VHA National Radiation Oncology Program recommends consideration of Veterans for Group 2 indications when the Veteran is enrolled in an Institutional Research Board (IRB)-approved study. The following Group 2 indications represent those disease sites for which evidence is accumulating to support eventual inclusion into ASTRO Group 1.
 - a. Non-T4 and resectable head and neck cancers:
 - b. Non-metastatic prostate cancer;
 - c. Breast cancer:
 - d. Thoracic malignancies, including non-metastatic primary lung and esophageal cancers;
 - e. Abdominal malignancies, including non-metastatic primary pancreatic, biliary and adrenal cancers;
 - f. Pelvic malignancies, including non-metastatic rectal, anal, bladder and cervical cancers.
- 5. It is the VHA position that proton therapy for ASTRO Group 2 indications should be conducted as a part of a clinical trial. As such, proton therapy will not be deemed appropriate for the routine treatment of Veterans diagnosed with ASTRO Group 2 presentations not enrolled on a therapeutic clinical trial. Specifically, proton therapy will not be used for organ-confined adenocarcinoma of the prostate

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- (OCAP). Preferred treatment modalities for OCAP include surgical resection, 3-D conformal external beam irradiation, intensity modulated radiation therapy, stereotactic body radiotherapy or brachytherapy.
- 6. In 2013, after reviewing all available medical literature, the VHA Health Services Research & Development Service's Evidence-based Synthesis Program agreed with ASTRO that clinical evidence did not support a general preference for proton therapy for Group 2 presentations. Today, on-going clinical trials are comparing proton versus photon therapy for breast and prostate cancers, tumors of the head and neck, esophagus and lung. VHA, through its National Radiation Oncology Program Office, will closely monitor these and other on-going investigations for the potential to improve cancer related outcomes for our Veterans through proton beam therapy.
- 7. Should you have additional questions, please contact Michael P. Hagan, M.D., Ph.D., National Director, Radiation Oncology Program by phone, at (804) 675-6270 or by email, at michael.hagan@va.gov or Wendy Kemp by email, at wendy.kemp@va.gov.

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