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Date of request: June 6, 2020
NCCN Guidelines Panel: Prostate Cancer Panel

On behalf of HALO Diagnostics, I respectfully request the NCCN Prostate Cancer Panel to review the enclosed data for inclusion of Laser Focal Therapy for the treatment of prostate cancer.

Specific Changes: Recommend Laser Focal Therapy using the Visualase® MRI-Guided Laser Ablation System for the treatment of intermediate risk organ confined prostate cancer and as a salvage therapy option for men with biochemical recurrence, in the prostate cancer treatment algorithm pages 47 and 48 under "Thermal Ablation" and "Clinical Trials".

FDA Clearance: The FDA cleared Visualase® MRI-Guided Laser Ablation System (510(k): K081656 and K071328) has been used in humans for the treatment of brain, bone (spine), thyroid, and liver cancers. This system is FDA cleared with broad, general indications, "The Visualase Thermal Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 800nm through 1064nm."

Along with the Visualase® MRI-Guided Laser Ablation System, the following FDA cleared devices are used in this procedure with broad indications including use in urology procedures to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery:

1. Visualase Cooled Laser Application System, Laser Diffusing Fiber, Cooling Catheter System, Bare Tip Fiber: 510(k): K053087
2. PhoTex1 5 Diode Laser Series: 980, 810, 940: 510(k): K060304
3. PhoTex3O Diode Laser Series, Model 980nm, 810nm, 940nm: 510(k): K092197
4. Visualase ENVISION Software System: 510(k): K063505

Rationale: HALO Diagnostics, formerly Desert Medical Imaging, is 10 years into a 20-year IRB approved phase II clinical trial. Recently published interim 10-year study results demonstrates oncological control similar to radical prostatectomy and superior functional outcomes in the treatment of naïve and salvage prostate cancer patients. Under an IRB-approved, HIPAA-compliant protocol, 158 men and 248 cancer foci were treated. No serious adverse events or morbidity were reported. Of the 122 men that underwent 6 mo. Biopsy of the treatment site, 32/122 (26%) of men were positive and clinically significant*, while 71/122 (59%) of men were negative. The remaining 18 men (15%) were positive but clinically insignificant. In addition, while most of the positive results were of marginal recurrence, 6 men (5%) had clinically significant incidence cancers. We observed a 37% decrease in mean PSA at 12 months post therapy and no statistically significant change in IPSS and SHIM scores. At ten years, the metastasis free survival rate is 99%, the prostate cancer specific survival rate is 100%, and the overall survival rate is 98%.
** Excludes Gleason score 3+3 (Grade Group 1).*

The following articles are submitted in support of this proposed change.

1. Feller J., Greenwood B., Jones W., Toth R., Gunberg S., Herz J., Outpatient Trans-Rectal MR-Guided Laser Focal Therapy Phase II Clinical Trial: Ten-year interim results, The Journal of Urology, Vol. 203, No. 4S, Supplement, e369 (2020).
2. Bomers JGR, Cornel EB, Fütterer JJ, et al. MRI-guided focal laser ablation for prostate cancer followed by radical prostatectomy: correlation of treatment effects with imaging. World J Urol. 2017;35(5):703-711. doi:10.1007/s00345-016-1924-1
3. van Luijtelaar, A., Greenwood, B.M., Ahmed, H.U. et al. Focal laser ablation as clinical treatment of prostate cancer: report from a Delphi consensus project. World J Urol 37, 2147–2153 (2019).

Sincerely,
Bernadette M. Greenwood