Brachytherapy/Protocol-Specific Procedure

Y-90 MicroSpheres (TheraSpheres®) for treatment of hepatocellular carcinoma

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Brachytherapy Device :	Y-90 TheraSpheres®
	Y-90 TheraSpheres® is a radioactive implant in the form of glass microspheres. The intended use of these microspheres is for implant into malignant hepatic tumors via catheter placed in the hepatic artery, distributing non-uniformly throughout the liver. The microspheres are impregnated with yttrium 90 (Y-90); a beta-emitting isotope that delivers the tumoricidal doses of radiation to the tumor.
Device Information Source:	Y-90 TheraSpheres® is indicated for the treatment of unresectable hepatocellular carcinoma. For additional information regarding this agent, consult package insert or other standard references
Applicability of Worksheet:	Clinical use of commercial product; standard of care
Target Patient Process:	Candidates for this procedure are patients who have hepatocellular carcinoma, considered to be non-resectable. Patients will be evaluated by Oncology, Radiation Oncology and Interventional Radiology staff prior to the procedure.
Administration/Treatment Schedule:	A patient is identified as a possible candidate through Oncology or Transplant. This patient is referred to IR for a consult to determine eligibility. A triphasic abdomen CT and lab tests are run. In addition, a 99m-Tc MAA scan is scheduled within 1 month before a therapy through nuclear medicine to determine the extent of pulmonary shunting. The Nuclear Medicine physician calculates the pulmonary shunt and the IR physician calculates the liver mass volume to be treated. These values are supplied to the Radiation Oncologist by the IR NP assigned to the case. The Radiation Oncologist completes the Y-90 TheraSpheres® Written Directive. Details are given in the attached Protocol.
Dose Range:	A Y-90 TheraSpheres® treatment is intended to expose the liver to 80 to 150 Gy. The IR physician and Radiation Oncologist prescribe the amount of Y-90 TheraSpheres® using the Y-90 TheraSpheres® Written Directive. This dose will be verified by Medical Physics. The prescribed dose should correspond to the doses provided by MDS-Nordion.
Necessary Training:	Initial training of a treatment team is provided by the manufacturer. Subsequent training from trained personnel is acceptable.
Scheduling Procedures:	Scheduling is coordinated through the assigned IR Nurse Practitioner. Details are given in the attached Protocol.
Written Directive and Validation:	The Radiation Oncologist will forward the written directive (Y-90 Labeled TheraSpheres® Written Directive) to medical physics after validating the dosage with the IR staff. Medical physics will fax or deliver the written directive to the nuclear pharmacy when the dose verification is complete. Doses cannot be ordered until this form is received by the nuclear pharmacy. The original of the form will be kept in Radiation Oncology.
Y-90 Procurement/Preparation:	Upon receipt of the Y-90 TheraSpheres® Written Directive from medical physics, the nuclear pharmacist will fill out the TheraSpheres® Order Form and email to TheraSpherecustomersupport@btgplc.com or fax the sheet to MDS-Nordion at (613) 591-7414. A confirmation will be faxed or emailed to the radiopharmacist within 24 hours. After ordering, the dose sheet and confirmation is attached to the order clips in the nuclear pharmacy and a notation is written on the nuclear medicine inventory blackboard.

The cut-off time for ordering is Tuesday at 12:00pm the week before a scheduled therapy.

The TheraSpheres® package should arrive at the Nuclear Pharmacy via Fed-Ex the day before the scheduled therapy. If the dose is late, the Nuclear Pharmacist will contact MDS-Nordion via the telephone number provided on the returned confirmation forms. The nuclear Pharmacist will also notify the nurse practitioner involved in the case (pager #6842).

Details for the preparation are given in the attached Protocol.

Pharmacy Product Validation:

MDS-Nordion will provide a NIST source to calibrate the dose calibrators in the nuclear pharmacy. This source will establish a reference for future TheraSpheres orders.
Measurements will also be made with a survey meter around the delivery apparatus, per standard check-in procedures.
For the therapy, the nuclear pharmacy will verify the activity using the dose calibrator. The medical physicist will re-verify the activity in the dose calibrator. Following verification of the assay, the Medical Physicist will take the source and the TheraSpheres administration kit to the IR room for assembly of the administration apparatus.

Upon completion of the procedure, the radionuclide vial, tubing and any other articles contaminated with radioactive materials will be returned to the nuclear pharmacy by the medical physicist, and the residual activities calculated based on a second set of survey measurement.

Patient Instructions/Education Validation: Patient instructions/Education validation done by the IR nurse practitioner assigned to the patient.

Administration Validation: Only appropriately trained individuals may administer this product. The source infusion is by DVI staff physician, with help from medical physics. The delivered activity is determine by the Medical Physicist.

Other information/instructions: See attached TheraSpheres Protocol which includes 6 attachments.

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