Radiopharmaceutical Therapy: Agent/Protocol-Specific Procedure

I-131 Sodium Iodide for Hyperthyroidism

Radiopharmaceutical Agent:

I-131 Sodium Iodide

I-131 sodium iodide is available as a stabilized aqueous solution or solid capsule form for oral administration. I-131 decays by beta emission (~90% of local irradiation) and associated gamma emission (~10% of local irradiation), with a physical half-life of 8.04 days.

Sodium iodide is readily absorbed from the gastrointestinal tract. Following absorption, it is distributed primarily within the extracellular fluid of the body. It is concentrated and organified by the thyroid and trapped but not organified by the stomach and salivary glands. It is promptly excreted by the kidneys.

Drug Information Source:

FDA approved for hyperthyroidism and carcinoma of the thyroid. 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:

Patient's with hyperthyroidism including Graves Disease, multiple hyperfunctioning nodules, solitary autonomous nodule, and subclinical hyperthyroidism.

Written Directive and Validation:

Authorized User will determine the appropriateness of the therapy based on the thyroid uptake, perform the necessary calculations, and complete the written directive as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**. Section B on the **Radiopharmaceutical Therapy Dose Documentation Form** "Patient Information/Education Verification" will be completed by the Authorized User **prior** to forwarding the **Radiopharmaceutical Therapy Dose Documentation Form** to Nuclear Pharmacy staff for drug procurement/preparation.

Administration/Treatment Schedule:

Patient Prep:

A 24-hour uptake is usually scheduled for a diagnostic I-131 sodium iodide dose administration 24 hours prior to therapy. If a thyroid uptake has been done within 3 months that result may be acceptable if approved by the Authorized User. Both uptake and therapy appointments should be made only for the morning unless otherwise agreed to by the Authorized User. For the therapy, allow 90 minutes, which includes physician consultation. For patients who are suspected of having a solitary toxic thyroid nodule or in whom there is difficulty in clinically deciding between nodular and Graves' disease, a Tc99m-pertechnetate thyroid scan is recommended. See the Department of Radiology Nuclear Medicine Division Thyroid Uptake and Thyroid Scan Protocols for details regarding these procedures.

Patients should be off propylthiouracil (PTU) for between 3-5 days (not less than 3 days or more than 5 days), prior to thyroid uptake and/or therapy.

Female Patients (Age 10 to 55 years):
Patients must have a pregnant test performed no greater than 24 hours prior to the administration.
Patients must not be breast feeding or have ceased breast feeding 3 to 6 months prior to therapy.

The uptake and therapy are affected by certain medications, iodine agents (eg. contrast dyes) and foods (eg. seaweed, kelp, sushi, miso soup, carrageen thickeners, and alginate wound care agents). See Radioactive Iodine Uptake Interactions document and Iodine Containing Foods document attached to the

Department of Radiology Nuclear Medicine Division Thyroid Uptake Protocol for detailed lists.

Patients must complete a thyroid questionnaire upon arrival to Nuclear Medicine.

Treatment:
A Nuclear Medicine physician will interpret the thyroid uptake and scan (if performed) and decide whether or not there is sufficient clinical indication for the therapy. If not, the Nuclear Medicine resident or faculty physician of the day will speak with the patient and/or referring physician as needed.

Prior to administration, the Nuclear Medicine physician will obtain written informed consent, and explain the treatment options to the patient. They must determine that the patient understands these options and implications and advise the patient about the incidence of re-treatment and the incidence of early and late hypothyroidism. The Nuclear Medicine physician will educate the patient regarding radiation safety issues associated with I-131 sodium iodide treatment. The Nuclear Medicine Physician will discuss the planned treatment with the administering clinician.

Administering clinicians must comply with the Department of Radiology Nuclear Medicine Division Personnel Bioassay Thyroid Counts policy.

Procedure:
1. Written directive is completed, and dose is prepared and administered as directed on the **Radiopharmaceutical Therapy Dose Documentation Form**.
2. Oral dose is given to patient in either capsule or liquid form. The Nuclear Medicine Faculty must be available when the dose is administered.
3. If a liquid form is given, the administration vessel in the lead pig should be sitting on a solid, sturdy surface for administration. Prior to administration, the Administering Clinician may add enough tap water to increase the volume, so the glass tube is approximately half full. Water should be added with care to avoid overfilling. After the patient drinks the dose, water should be added two more times to rinse the vessel and ensure the entire dose was administered. The patient should keep their mouth on the straw, and the straw in the glass tube while the water is added to avoid any dripping of I-131 sodium iodide solution.
4. The following will be surveyed with a GM counter and disposed of appropriately by the Administering Clinician: (includes, but is not limited to) gloves, chucks, paper towels, sterile fields.
5. Dispose of contaminated supplies in a long-lived isotope waste container.
6. The administration area and will be surveyed with a GM counter after the patient is discharged from area/department.

Exposure Calculations/Release Criteria: Calculations must be completed as directed on the **Radiopharmaceutical Therapy Dose Documentation Form** in Section E: "I-131 Therapy Calculation & Justification Record for Exposure from the Patient". The Administering Clinician should perform calculations and complete the form where indicated before the patient is released. Final dose calibrator assay should be used for all calculations. Estimated maximum dose to an individual exposed to the patient must not exceed 500 mrem (0.5 rem or 5 mSv).

A. Doses Less Than or Equal to 33 mCi
(Reference: WisReg 1556, Vol 9, Table 22: "WI Chapter 157 – Radiation Protection Regulatory Guide")
Exposure will be less than 500 mrem (5 mSv) with any administered activity less than or equal to 33mCi.

Calculate the estimated exposure based on the following equation extrapolated from Table 22:

$$\textit{Exposure (mrem)} = 15.15\ \textit{mrem} \times \textit{Administered Activity (mCi)}$$

B. Patient Specific Dose Calculations for Doses Greater than 33 mCi
(Reference: "NRC Regulatory Guide 8.39 – Release of Patients Administered Radioactive Materials", Equation B-5 – used per State of Wisconsin Regulations HFS 157.62.8)

Doses greater than 33 mCi may be given in some cases. Patient specific exposure calculations must be done by the Authorized User, before the patient is released, using the following equation:

$$Exposure(rem) = \frac{34.6\Gamma Q_o}{(100cm)^2}\{E_1 T_p(0.8)(1-e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p}E_2F_1T_{1eff} + e^{-0.693(0.33)/T_P}E_2F_2T_{2eff}\}$$

Patient Specific Characteristics:
F_1 (Extra-thyroid uptake fraction) = measured
F_2 (Thyroid uptake fraction) = measured

Constants:
Conversion Factor = 34.6
Γ (Gamma Ray Constant for I-131) = 2.2
T_P (Physical Half-life for I-131) = 8.04 days

Assumptions:
T_{1eff} (Extra-thyroid effective half-life) = 0.32 days
T_{2eff} (Thyroid effective half-life) = 5.2 days
E_1 (Occupancy factor for first 8 hours) = 0.75
E_2 (Occupancy factor from 8 hours to total decay) = 0.25

A spreadsheet may be used to aid in the calculation of this equation. Available at: J:\Nuclear\Nuclear Pharmacy\NRC & Safety & Dosimetry\I131 Exposure\ I-131 Hyperthyroidism Exposure Calculation.xls

Dose Range:

Adult Desired Dose Delivered to Thyroid Gland (µCi/gram):

Graves Disease	80-100 µCi/gram
with multiple hyperfunctioning nodules	150-200 µCi/gram
with nontoxic multinodular goiter	100-200 µCi/gram

Pediatric Desired Dose Delivered to Thyroid Gland (µCi/gram):
150 µCi/gram (Higher dose due to resistance of the thyroid gland to therapy)

The prescribed dose is calculated by multiplying the estimated thyroid mass (estimated by palpation) in grams by the desired dose, divided by the 24-hour uptake x 100%.

$$\text{Prescribed Dose (µCi)} = \frac{\text{Mass of Gland (g)} \times \text{Desired Dose (µCi/g)}}{\text{Uptake at 24 hours}} \times 100\%$$

For a toxic hot nodule, provided there is suppression of the rest of the gland, a suggested empiric dose is 15 mCi. Alternatively, one can use the thyroid uptake result and give 10 mCi to the autonomous thyroid tissue. All doses are subject to adjustment based on the prescribing physician's clinical judgment.

Scheduling Procedures:	Referring clinician will enter an order for NM THERAPY RADIOPHARMACEUTICAL ORAL HYPERTHYROID INITIAL OR RETREATMENT via Health Link for this therapy. The referring clinic schedulers will call Radiology/Nuclear Medicine schedulers to schedule this order. A Nuclear Medicine or Radiology resident will protocol the order via the Health Link Protocol Worklist work que and fill out the I-131 Therapy Consults form. The order and I-131 Therapy Consults form are then review with the Nuclear Medicine staff for approval
Drug Procurement/Preparation:	All individuals involved in the preparation or verification of I-131 sodium iodide must comply with the Radiology Department Nuclear Medicine Division Personnel Bioassay Thyroid Counts policy. Order entry and dose preparation will be documented as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**. Upon receipt of the written directive, Nuclear Pharmacy staff will determine whether they choose to prepare the dose in house or order a unit dose from a Contracted Nuclear Pharmacy. For solution doses prepared in house, all manipulations will occur in a fume hood or SmartFill Unit. The appropriate dose will be drawn up from a stock vial of I-131 sodium iodide and placed into a test tube or equivalent vessel. Any dilution will be done with water step. The vessel containing the dose will be placed in a lead shield for dispensing. For Capsule doses prepared in house, all manipulations of RAM will occur in a fume hood or SmartFill Unit. If a dose needs to be ordered from a Contracted Nuclear Pharmacy, Nuclear Pharmacy staff will place the order via phone. A time estimate for receipt of the dose will be communicated to the Administering Clinician. This should be used with extenuating circumstances as it is more expensive than in-house compounding.
Pharmacy Product Validation:	As instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**. The verification of the product will include placement of the dose into the dose calibrator, and comparison of the assay to the product label generated at the completion of dose assay, as well as the written directive. If a dose was prepared in house, the administering clinician will confirm that the dose was drawn from an I-131 sodium iodide stock vial in the fume hood, the proper isotope is selected on the dose calibrator, and that the displayed dose is within 10% of the prescribed dose. If a unit dose was ordered from Cardinal Health, the verification of the product will also include comparison of the assay to the Contracted Nuclear Pharmacy's radiopharmaceutical label.
Patient Instructions/Education Validation:	I-131 Sodium Iodide Health Facts For You will be reviewed with and given to the patient as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**; no additional procedures required
Administration Validation:	Only appropriately trained individuals may administer this product. Complete and document administration as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form**. Administering clinicians must comply with the Department of Radiology Nuclear Medicine Division Personnel Bioassay Thyroid Counts policy.

Other information/instructions:	The uptake and therapy are both reported in the physician dictation. In addition, the report should include if the patient should remain on drug therapy (propranolol) or restart-PTU (usually 3 days later), and when he or she should be seen in clinic or at the patient's own primary or referring physician's office. If for any reason the patient must be admitted to UW Hospital within 96 hours of treatment, the **Radiopharmaceutical Therapy: Agent/Protocol-Specific Procedure for I-131 Sodium Iodide for Inpatient Use** should be followed.

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