Radiopharmaceutical Therapy: Agent/Protocol-Specific Procedure

Samarium (Sm-153) Lexidronam for Bone Pain

Radiopharmaceutical Agent:

Samarium (Sm-153) Lexidronam (Quadramet®)

Quadramet® is a radiopharmaceutical consisting of stable complexes of radioactive Samarium (Sm-153) and tetraphosphonate chelators (EDTMP). Sm-153 has a half life of 46.3 hours and emits both beta and gamma radiation. The gamma radiation can be used to follow the uptake of the radionuclide in vivo, whereas the beta radiation provides the therapeutic use of the compound.

Quadramet® has a high affinity to the skeleton and concentrates after intravenous injection in areas of elevated bone turnover (osteoblastic lesions). It is indicated as a palliative measure for the relief of pain from metastatic lesions that enhance on bone scans. The onset of pain relief observed with Quadramet® is rapid, about one week after injection.

Drug Information Source:

FDA approved for palliation of bone pain. 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:

Patients with pain secondary to cancer metastatic to bones with activity demonstrated on bone scan. Osteosarcoma patients are treated under a different protocol.
Patients must have had a CBC/platelet count within the past 7 days. The results must be verified by the staffing nuclear medicine physician.

Administration/Treatment Schedule:

Patient Prep:
Immediately before administration, the patient is hydrated with approximately 500mL of normal saline.

Clinical staff will ascertain whether the patient is continent. If the patient is incontinent, precautions will be explained. A Health Facts for You for Quadramet® (Samarium Sm-153 Lexidronam Injection) will distributed to the patient.

Treatment:
The treating Radiation Oncologist, Nuclear Medicine Physician, Nuclear Medicine Technologist, or the Medical Physicist will perform the injection.

Procedure:

1. Written directive is completed and dose is prepared and administered as directed on the **Radiopharmaceutical Therapy Dose Documentation Form specific for Sm-153**.
2. Injection is through the existing IV line. An initial test injection is first administered, comprising of about 0.1 mL of the dose.
3. Following the test injection, the Administering Clinician, Medical Physicist or Radiation Safety Department Representative will survey the patient's chest with a GM meter on the surface, above the heart, to confirm activity has been carried from the injection site through the circulatory system.
4. Following positive indications of patency of the IV line, the remaining solution is injected via IV push over approximately 2 minutes.
5. Following the injection, an additional 250mL of normal saline is run through the IV line.
6. The clinician removes the IV line.

Exposure Calculations/Release Criteria:

Measurement of the exposure rate from the patient is made with a GM meter at 1 meter. Patients with exposure rates less than 0.3 mSv/h (30 mR/h) at 1 meter, or patients receiving less than 700 mCi may be released (Appendix A). If patients has exposures above 0.05 mSv/h (5 mR/h) will receive instruction on radiation precautions. (Appendix B)

Dose Range:

Actual body weight is used for all calculations.

Routine use – not concurrent with external beam radiotherapy:
1 mCi/kg
Treatment may be repeated contingent on blood counts and other therapies given

Fractionated –concurrent with external beam radiotherapy:
0.25 mCi/kg
Treatments may be repeated three times or more depending on the patient's response to treatment and blood counts, as determined by Physician.

Scheduling Procedures:

For Radiation Oncology Patients: Radiation Oncology clinic staff will contact Nuclear Pharmacy staff via phone, email or in person to confirm drug availability. At least 48 hours advanced notice is required. Radiation Oncology clinic staff will hand deliver the Written Directive to the Nuclear Pharmacy for ordering. Nuclear Medicine scheduling is not involved.

For Nuclear Medicine Patients: Oncology Clinic schedulers will contact the Nuclear Medicine scheduling staff with a request for a Samarium-153 therapy. The Nuclear Medicine schedulers will record information in a Health Link in-basket message to the Nuclear Medicine Technologists. Upon receipt of the in-basket message, the Lead Nuclear Medicine Technologist will attach the written Directive and deliver to Nuclear Medicine Staff Physician for approval. After approval, the Nuclear Pharmacy is contacted to check availability of drug. The Lead Nuclear Medicine Technologist will then schedule the therapy. The ordering clinic will then be contacted with the date and time**.**

Written Directive and Validation:

Authorized User will determine the appropriateness of the therapy based on the clinical presentation, perform the necessary calculations, and complete the written directive as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form specific for Sm-153**; no additional procedures required.

Drug Procurement/Preparation:

Upon receipt of written directive, the Nuclear Pharmacy staff will order the radionuclide directly from the manufacturer (Berlex). The product will arrive at the radiopharmacy, frozen, via Fed-Ex. Verify with the manufacturer availability and day of delivery.

Nuclear Pharmacy staff may order a unit dose via phone/FAX from: Cardinal Health, for a premium price.

153 East Badger Road
Madison, WI 53713
608-270-2670
FAX 608-270-3572

Nuclear Pharmacy staff will place the order via phone, and confirm by FAXing a copy of the written directive. A time estimate for receipt of the dose will be communicated to Radiation Oncology clinic staff.

Quadramet® is available for administration on the following days:

Wednesdays, 1300 or later
Thursdays, any time of day
Fridays, expires at 1100

Orders must be placed at least 48 hours in advance and are subject to availability. Cancellations are guaranteed to be reimbursed only if Cardinal Health has not received the Quadramet® from the vendor, usually 24-48 hours prior to the day of

administration. Reimbursement may occur if Cardinal Health can obtain a refund from the vendor or can sell the dose to another customer. Initial preparation of the drug (thawing the frozen product) begins approximately 6 hours prior to administration and must be used within 8 hours of thawing. Therefore, same day cancellations are unlikely to be reimbursed.

Pharmacy Product Validation: As instructed on the **Radiopharmaceutical Therapy Dose Documentation Form specific for Sm-153**. The vial subtraction method will be used to assay the dose. Verification can be made by calculating the difference between the calculated original activity of the vial and the activity in the vial after withdrawing the dose.

The verification of a product from an outside vendor will include placement of the dose into the dose calibrator, and comparison of the assay to the vendor's radiopharmaceutical label.

Patient Instructions/Education Validation: Patient Health Facts for You (Appendix B) will be distributed to all patients at time of consultation. Patients will be told to flush the toilet twice after use for the next two days, and to minimize contact with children for the following 5 days. Incontinent patients will be instructed in appropriate disposal of used pads.

Administration Validation: Only appropriately trained individuals may administer this product. Complete and document administration as instructed on the **Radiopharmaceutical Therapy Dose Documentation Form specific for Sm-153**.

Other information/instructions: Patients admitted to the hospital within two days following this therapy will be assessed for the need for radiation isolation with standard radiation isolation orders issued, regardless of whether or not radiation precautions are required. Refer to UWHC Policy for Patients who Received Therapeutic Radiopharmaceuticals and Need to be Admitted to the Hospital.

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