Lymphoseek

(technetium Tc 99m tilmanocept) Injection

Dear Formulary Committee,

Attached please find the formulary kit for Lymphoseek® (technetium Tc 99m tilmanocept) injection, a lymphatic mapping agent indicated, with or without scintigraphic imaging, for lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors when used as a component of surgical management, as well as guiding sentinel lymph node biopsy in patients with clinically node negative squamous cell carcinoma of the oral cavity, breast cancer, or melanoma.

The components of the formulary kit include:

- FDA approval letter
- Clinical summary
- Dosing and administration guidelines
- Ordering and contact information
- Coding and reimbursement information
- Full prescribing information
- Material Safety Data Sheet (MSDS)

Depending upon your needs, please download the appropriate components you require or the entire kit.

Indication:

Lymphoseek (technetium Tc 99m tilmanocept) injection is indicated, with or without scintigraphic imaging for:

- Lymphatic mapping using a handheld gamma counter to locate lymph nodes draining a primary tumor site in patients with solid tumors for which this procedure is a component of intraoperative management.
- Guiding sentinel lymph node biopsy using a handheld gamma counter in patients with clinically node negative squamous cell carcinoma of the oral cavity, breast cancer or melanoma

Important Safety Information:

In clinical trials with Lymphoseek, no serious hypersensitivity reactions were reported, however Lymphoseek may pose a risk of such reactions due to its chemical similarity to dextran. Serious hypersensitivity reactions have been associated with dextran and modified forms of dextran (such as iron dextran drugs).

Prior to the administration of Lymphoseek, patients should be asked about previous hypersensitivity reactions to drugs, in particular dextran and modified forms of dextran. Resuscitation equipment and trained personnel should be available at the time of Lymphoseek administration, and patients observed for signs or symptoms of hypersensitivity following injection.

Any radiation-emitting product may increase the risk for cancer. Adhere to dose recommendations and ensure safe handling to minimize the risk for excessive radiation exposure to patients or health care workers.

In clinical trials, no patients experienced serious adverse reactions and the most common adverse reactions were injection site irritation and/or pain (<1%).

Full prescribing information is available at
http://lymphoseek.com/assets/pdfs/Lymphoseek%20Package%20Insert%20-%20October%202014.pdf

Please contact your local Cardinal Health Sales Consultant if you need further information.

Thank you for visiting www.lymphoseek.com.