Lymphoseek® (technetium Tc 99m tilmanocept) Injection Coding Information

Product Coding

As of January 1, 2014, to report the supply of Lymphoseek® (technetium Tc 99m tilmanocept) injection:

A9520 Technetium Tc-99m tilmanocept, diagnostic, up to 0.5 millicuries

Procedure Coding

To report 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 or for 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, providers should use the Current Procedural Terminology (CPT®) code that is most specific for the procedure. Potentially relevant codes can be found by visiting the Society of Nuclear Medicine and Molecular Imaging's (SNMMI) Coding Corner at http://interactive.snm.org/index.cfm?PageID=4816.

CPT codes commonly used with lymphoscintigraphy and/or lymphatic mapping include:

38792	Injection procedure; radioactive tracer for identification of sentinel node
78195	Lymphatics and lymph node imaging

Current Procedural Terminology (CPT®) is copyright 2016, American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. The American Medical Association assumes no liability for data contained or not contained herein.

See Important Safety Information and Disclaimer on page 6.

Diagnosis Coding

Providers should select the most appropriate ICD-10 code(s) with the highest level of detail to describe the patient's condition. Any questions should be directed to the pertinent local payer. The diagnosis of regional lymphatic disease in patients with breast cancer, melanoma, or squamous cell carcinoma of oral cavity may be reported under the following codes:

Breast Cancer: Female Breast

C50.019 – Malignant neoplasm of nipple and areola, unspecified female breast

C50.119 – Malignant neoplasm of central portion of unspecified female breast

C50.219 – Malignant neoplasm of upper-inner quadrant of unspecified female breast

C50.319 – Malignant neoplasm of lower-inner quadrant of unspecified female breast

C50.419 – Malignant neoplasm of upper-outer quadrant of unspecified female breast

C50.519 – Malignant neoplasm of lower-outer quadrant of unspecified female breast

C50.619 – Malignant neoplasm of axillary tail of unspecified female breast

C50.819 – Malignant neoplasm of overlapping sites of unspecified female breast

C50.919 – Malignant neoplasm of unspecified site of unspecified female breast

Breast Cancer: Male Breast

C50.029 – Malignant neoplasm of nipple and areola, unspecified male breast

C50.929 – Malignant neoplasm of unspecified site of unspecified male breast

Breast Cancer: Secondary & In-Situ

C79.81 – Secondary malignant neoplasm of breast

D05.90 – Unspecified type of carcinoma in situ of unspecified breast

See Important Safety Information and Disclaimer on page 6.

Malignant Melanoma of the Skin:

C43.0 – Malignant melanoma of lip
C43.10 – Malignant melanoma of unspecified eyelid, including canthus
C43.20 – Malignant melanoma of unspecified ear and external auricular canal
C43.30 – Malignant melanoma of unspecified part of face
C43.31 – Malignant melanoma of nose
C43.39 – Malignant melanoma of other parts of face
C43.4 – Malignant melanoma of scalp and neck
C43.59 – Malignant melanoma of other part of trunk
C43.60 – Malignant melanoma of unspecified upper limb, including shoulder
C43.70 – Malignant melanoma of unspecified lower limb, including hip
C43.8 – Malignant melanoma of overlapping sites of skin
C43.9 – Malignant melanoma of skin, unspecified

Melanoma In Situ:

D03.0 – Melanoma in situ of lip
D03.10 – Melanoma in situ of unspecified eyelid, including canthus
D03.11 – Melanoma in situ of right eyelid, including canthus
D03.12 – Melanoma in situ of left eyelid, including canthus
D03.20 – Melanoma in situ of unspecified ear and external auricular canal
D03.21 – Melanoma in situ of right ear and external auricular canal
D03.22 – Melanoma in situ of left ear and external auricular canal
D03.30 – Melanoma in situ of unspecified part of face
D03.39 – Melanoma in situ of other parts of face
D03.4 – Melanoma in situ of scalp and neck
D03.51 – Melanoma in situ of anal skin
D03.52 – Melanoma in situ of breast (skin) (soft tissue)
D03.59 – Melanoma in situ of other part of trunk
D03.60 – Melanoma in situ of unspecified upper limb, including shoulder
D03.61 – Melanoma in situ of right upper limb, including shoulder
D03.62 – Melanoma in situ of left upper limb, including shoulder

See Important Safety Information and Disclaimer on page 6.

D03.70 – Melanoma in situ of unspecified lower limb, including hip

D03.71 – Melanoma in situ of right lower limb, including hip

D03.72 – Melanoma in situ of left lower limb, including hip

D03.8 – Melanoma in situ of other sites

D03.9 – Melanoma in situ, unspecified

Malignant Neoplasm of Oral Cavity – Tongue

C01 – Malignant neoplasm of base of tongue

C02.0 – Malignant neoplasm of dorsal surface of tongue

C02.1 – Malignant neoplasm of border of tongue

C02.2 – Malignant neoplasm of ventral surface of tongue

C02.3 – Malignant neoplasm of anterior two-thirds of tongue, part unspecified

C02.4 – Malignant neoplasm of lingual tonsil

C02.8 – Malignant neoplasm of overlapping sites of tongue

C02.9 – Malignant neoplasm of tongue, unspecified

Malignant Neoplasm of Oral Cavity – Gum

C03.0 – Malignant neoplasm of upper gum

C03.1 – Malignant neoplasm of lower gum

C03.9 – Malignant neoplasm of gum, unspecified

Malignant Neoplasm of Oral Cavity – Floor of Mouth

C04.0 – Malignant neoplasm of anterior floor of mouth

C04.1 – Malignant neoplasm of lateral floor of mouth

C04.8 – Malignant neoplasm of overlapping sites of floor of mouth

C04.9 – Malignant neoplasm of floor of mouth, unspecified

See Important Safety Information and Disclaimer on page 6.

Malignant Neoplasm of Oral Cavity – Other and Unspecified Parts of Mouth

- **C05.0 – Malignant neoplasm of hard palate**
- **C05.1 – Malignant neoplasm of soft palate**
- **C05.2 – Malignant neoplasm of uvula**
- **C05.8 – Malignant neoplasm of overlapping sites of palate**
- **C05.9 – Malignant neoplasm of palate, unspecified**
- **C06.0 – Malignant neoplasm of cheek mucosa**
- **C06.1 – Malignant neoplasm of vestibule of mouth**
- **C06.2 – Malignant neoplasm of retromolar area**
- **C06.80 – Malignant neoplasm of overlapping sites of unspecified parts of mouth**
- **C06.89 – Malignant neoplasm of overlapping sites of other parts of mouth**
- **C06.9 – Malignant neoplasm of mouth, unspecified**

See Important Safety Information and Disclaimer on page 6.

Indication:

Lymphoseek (technetium Tc 99m tilmanocept) injection is a radioactive diagnostic 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 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%).

For full prescribing information, please visit
http://lymphoseek.com/assets/pdfs/Lymphoseek%20Package%20Insert%20-%20October%202014.pdf

Disclaimer: This coding information is based upon publicly available information and is current as of January 7, 2016. This document is subject to change without notice. This information is provided for educational purposes only and is not intended to be coding advice. Navidea Biopharmaceuticals cannot guarantee that any product or service billed with the codes listed in this document will be covered or, if covered, the amount that will be paid by any payer. It is the responsibility of the provider to select appropriate codes for each patient and to submit appropriate codes, charges, and modifiers for services rendered. Providers should contact insurers to verify correct coding procedures prior to submitting claims related to Lymphoseek® administration. In all cases, providers must bill according to the rules, policies and procedures of individual payers. To be eligible for coverage, a product or service must be medically necessary, the product furnished or service provided must be described by the nomenclature of the code reported and the medical record should document that the product or procedure was medically necessary and furnished or performed as reported. If you have any questions about appropriate billing for products or services, please consult your local payer.

See Important Safety Information and Disclaimer on page 6.