



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0245

Subject **ProstaScint®**

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Hyperlink to Related Coverage Policies

Nuclear Imaging including Single-Photon Emission Tomography (SPECT)
Tumor Markers for Diagnosis and Management of Cancer

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA covers ProstaScint® (Indium-111 labeled capromab pendetide) as medically necessary for use in EITHER of the following:

- newly diagnosed individuals with biopsy-proven prostate cancer, thought to be clinically localized after standard diagnostic evaluation, who are at high risk for pelvic lymph node metastases
- individuals previously treated for prostate cancer (e.g., radiation therapy, surgery) with detectable or rising prostate-specific antigen (PSA) levels and negative or equivocal standard metastatic evaluations in whom there is a high clinical suspicion of occult metastatic disease

General Background

Among the body's natural defenses against infectious agents (i.e., antigens) are antibodies, proteins that seek out the antigens and help destroy them. In monoclonal antibody production technology, tumor cells that can replicate endlessly are fused with mammalian cells that produce antibodies. Each monoclonal antibody (MAb) recognizes different proteins on specific cancer cells. MAbs are approved as biologics by the U.S. Food and Drug Administration (FDA). MAbs may be used in any of the following ways:

- alone (once bound to their targets, they trigger the body's normal effector mechanisms)
- coupled with fluorescent molecules to aid in imaging the targets
- coupled with drugs, toxins or radioactive materials to aid in killing the target directly

Note: For discussion of MABs used in cancer treatment, refer to the CIGNA Coverage Policy Tumor Markers for Diagnosis and Management of Cancer.

The search for techniques with greater sensitivity for detecting small, subclinical tumor deposits and improved specificity for distinguishing between malignant and benign masses has led to the development of techniques for linking radioactive labels to tumor-specific antibodies. MAb imaging (i.e., radioimmunoscinigraphy [RIS], immunoscintigraphy) is a nuclear imaging procedure that uses a radiolabeled monoclonal antibody as the radiopharmaceutical for the detection of an antigen expressed by a lesion.

U.S. Food and Drug Administration (FDA)

ProstaScint[®] is manufactured by EUSA Pharma Ltd. (Oxford, England). EUSA Pharma purchased Cytogen Corporation (Princeton, NJ) in 2009. Capromab pendetide labeled with indium-111 is an MAb that recognizes prostate-specific membrane antigen (PSMA), a substance found only in normal and cancerous prostate cells. It is FDA-approved (1996) as an imaging agent for use “in newly diagnosed patients with biopsy-proven prostate cancer, thought to be clinically localized after standard diagnostic evaluation, who are at high risk for pelvic lymph node metastases, and in post- prostatectomy patients with a rising prostate-specific antigen (PSA) and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease” (FDA, 1996).

Literature Review

Evidence in the peer-reviewed scientific literature supports the use of immunoscintigraphy with ProstaScint in prostate cancer patients at high risk or high clinical suspicion for metastatic disease. Although there is a lack of prospective studies comparing ProstaScint with other modern imaging techniques, the studies that have been conducted demonstrate that ProstaScint scans aid in the diagnosis of abdominal, retroperitoneal, and/or lymph nodes metastases in a subset of individuals. Researchers caution, however, that treatment decisions should not be based on ProstaScint scan findings alone but in addition to other risk factors such as PSA and Gleason score; the combination of factors significantly improves the prediction of metastatic disease (Haseman, et al., 2007; Raj, et al., 2002; Sodee, et al., 2000; Manyak, et al., 1999; Polascik, et al., 1999; Kahn, et al., 1998).

Professional Societies/Organizations

The National Comprehensive Cancer Network (NCCN) Prostate Cancer Clinical Practice Guideline (v.2.2009) addresses ProstaScint scan as an option under ‘Salvage Workup’ and ‘Postradiation Recurrence’ (NCCN, 2009).

The American College of Radiology Practice Guideline for the performance of tumor scintigraphy (amended 2006) discusses the dosage and specifications for the SPECT examination with ¹¹¹In-capromab pendetide.

Summary

Monoclonal antibodies (MAb), though more commonly used in immunotherapy than in diagnosis, are used in imaging (i.e., radioimmunoscinigraphy [RIS], immunoscintigraphy) to target certain cancer cells. While studies have generally been retrospective in design, the overall body of evidence in the published, peer-reviewed scientific literature indicates that the use of ProstaScint[®] (Indium-111 labeled capromab pendetide) is an effective diagnostic tool in a carefully selected subset of individuals with prostate cancer.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
78800	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area

HCPCS Codes	Description
A9507	Indium In-111 capromab pentetide, diagnostic, per study dose, up to 10 millicuries

ICD-9-CM Diagnosis Codes	Description
185	Malignant neoplasm of prostate
233.4	Carcinoma in situ of prostate
790.93	Elevated prostate specific antigen (PSA)
V10.46	Personal history of malignant neoplasm of prostate

***Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.**

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<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalsApplications/TherapeuticBiologicApplications/ucm080734.htm>

Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	12/15/2007	0245	ProstaScint®

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.