

WellCare Health Plans, Inc.
The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

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Harmony Behavioral Health, Inc.

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WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

AcuTect™ Scintigraphic Imaging for Deep Vein Thrombosis

Guideline Number: HS-132

Original Effective Date: 9/17/2009

Revision Date: n/a

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

AcuTect™ scintigraphic imaging for the detection of lower limb deep vein thrombosis (DVT) is considered experimental and investigational.

BACKGROUND

Diagnostic tests for deep vein thrombosis (DVT) include a D-dimer (blood) test, venous ultrasonography (US), and conventional venography. Contrast venography is the most sensitive and accurate test for diagnosis of DVT and is regarded as the gold standard. Patients with a low pretest probability of DVT and a positive D-dimer assay usually receive an ultrasound to confirm the diagnosis of DVT. Patients with moderate or high pretest probability have a 15–70% risk of DVT. Venous Doppler ultrasound is generally ordered as the first test because of the high incidence of DVT in this population. In patients with a prior history of deep venous thrombosis, it can be difficult to distinguish acute from old thrombus on conventional imaging modalities.

AcuTect (Diatide, Inc., Londonderry, NH) is a complex of a small-molecule synthetic peptide, apcitide, and the radionuclide, technetium (Tc) 99m (a gamma ray emitter). Apcitide binds preferentially to glycoprotein IIb/IIIa receptors, which are expressed on the surface of activated platelets, a major component of active thrombus formation. Thus, it may localize at sites where blood clots are present or forming. AcuTect is approved for use in the scintigraphic imaging of acute (not chronic) venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis. It allows for early (10 - 60 minutes post-injection, administered by injection into the antecubital vein) imaging of DVT of the entire lower extremities, including the calf.

Data supporting AcuTect scintigraphic imaging are lacking. Taillefer et al. (2000) conducted a Phase III multicenter clinical trial to compare 99mTc-apcitide scintigraphy with contrast venography for imaging acute DVT. A total of 243 patients were within ten days of onset of signs and symptoms of acute DVT or within ten days of surgery associated with a high risk of DVT. Of the 243 patients, 236 (85%) had images that were evaluable by both AcuTect and contrast venography. Readings of the 99mTc-apcitide scintigrams were compared to contrast venograms. Results showed a sensitivity range of between 73.4% and 75.5% and specificity range of between 67.5% and 72.8% for AcuTect. The trial population included patients with a history of DVT who may have had old, non-acute venous thrombi, so a subset of patients (n=63) having no

history of DVT or pulmonary embolism and who presented within three days of onset of signs and symptoms were also evaluated. In these patients, the results of 99mTc-apcitide scintigraphy, compared with contrast venography, showed a sensitivity of 90.6% and a specificity of 83.9%. There is insufficient evidence in the published, peer-reviewed scientific literature to support AcuTect scintigraphic imaging.

There are insufficient data in the peer-reviewed literature validating the diagnostic utility of AcuTect scintigraphic imaging or comparing its diagnostic utility to those of contrast venography or ultrasound. Contrast venography is the most sensitive and accurate test for diagnosis of deep vein thrombosis and is regarded as the gold standard.

CODING

AcuTect™ scintigraphic imaging for the detection of lower limb deep vein thrombosis (DVT) is considered experimental and investigational

Non Covered CPT codes

78456 Acute Venous thrombosis imaging, peptide

ICD-0-CM Procedure Codes

No applicable codes.

Non Covered HCPCS Code

A9504 Technetium Tc-99m apcitide, diagnostic, per study dose, up to 20 millicuries

Non Covered ICD-9 Diagnosis Codes

451.11 - 451.2 Phlebitis and thrombophlebitis of deep vessels of lower extremities
451.81 - 451.9 Phlebitis and thrombophlebitis of other sites
453.0 - 453.9 Other venous embolism and thrombosis
671.20 - 671.94 Venous complications in pregnancy and the puerperium, superficial thrombophlebitis, deep phlebothrombosis, antepartum, deep phlebothrombosis, postpartum, other phlebitis and thrombosis, other and unspecified venous complications

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