Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

Staywell of Florida

WellCare (Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

AcuTect™ Scintigraphic Imaging for Deep Vein Thrombosis

Policy Number: HS-132

Original Effective Date: 9/17/2009

Revised Date(s): 9/24/2010; 9/1/2011; 7/5/2012; 7/11/2013; 7/10/2014; 6/4/2015; 11/3/2016; 9/7/2017

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.

DISCLAIMER

The Clinical Coverage Guideline (CCG) 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 CCG. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the CCG. Additionally, CCGs 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 CCG 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. All links are current at time of approval by the Medical Policy Committee (MPC). Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com – select the Provider tab, then "Tools" and "Clinical Guidelines".

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., Londenderry, 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.

POSITION STATEMENT

Applicable To:

- ☑ Medicaid – All Markets
- ☑ Medicare – All Markets

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

CODING

Non Covered CPT© Code*

78456 Acute Venous thrombosis imaging, peptide

Non Covered HCPCS Level II © Code*

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

Non Covered ICD-10-PCS Codes

Refer to the following ICD-10-PCS table(s) for specific PCS code assignment based on physician documentation.

NOTE: Per ICD-10-PCS Coding Guidelines, "ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code".

B50 Imaging, Veins, Plain Radiography

B51 Imaging, Veins, Fluoroscopy

Non Covered ICD-10-CM Diagnosis Codes

I80.10 - I80.13 Phlebitis and thrombophlebitis of femoral vein

Original Effective Date: 9/17/2009 - Revised: 9/24/2010, 9/1/2011, 7/5/2012, 7/11/2013, 7/10/2014, 6/4/2015, 11/3/2016, 9/7/2017

I80.201 - I80.9	Phlebitis and thrombophlebitis of other and unspecified deep vessels of lower extremities
I82.401 - I82.409	Acute embolism and thrombosis of unspecified deep veins of lower extremity
I82.491 - I82.499	Acute embolism and thrombosis of other specified deep vein of lower extremity
I82.4Y1 - I82.4Y9	Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity
I82.4Z1 - I82.4Z9	Acute embolism and thrombosis of unspecified deep veins of distal lower extremity
I82.501 - I82.509	Chronic embolism and thrombosis of unspecified deep veins of lower extremity
I82.591 - I82.599	Chronic embolism and thrombosis of other specified deep vein of lower extremity
I82.5Y1 - I82.5Y9	Chronic embolism and thrombosis of unspecified deep veins of proximal lower extremity
I82.5Z1 - I82.5Z9	Chronic embolism and thrombosis of unspecified deep veins of distal lower extremity
I82.621 - I82.629	Acute embolism and thrombosis of deep veins of upper extremity
I82.721 - I82.729	Chronic embolism and thrombosis of deep veins of upper extremity
O22.30 - O22.33	Deep phlebothrombosis in pregnancy
O87.1	Deep phlebothrombosis in the puerperium

REFERENCES

1. Taillefer, R. (2001). Radiolabeled peptides in the detection of deep venous thrombosis. *Seminars in Nuclear Medicine, 31*(2), 102-123.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
9/7/2017, 11/3/2016, 6/4/2015, 7/10/2014, 7/11/2013, 7/5/2012	• Approved by MPC. No changes.
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC.