A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health

Submission Date: 09/01/2019

Policy Number: 0414

Effective Date: 

Revision Date: 

Policy Name: AcuTect Scintigraphic Imaging for Detection of Lower Limb Deep Vein Thrombosis

Type of Submission – Check all that apply:

☐ New Policy
☐ Revised Policy*
☒ Annual Review – No Revisions
☐ Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

CPB 0414 AcuTect Scintigraphic Imaging for Detection of Lower Limb Deep Vein Thrombosis

Clinical content was never revised. No additional non-clinical updates were made by Corporate since the last PARP submission.

Name of Authorized Individual (Please type or print):

Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:

Revised July 22, 2019
AcuTect Scintigraphic Imaging for Detection of Lower Limb Deep Vein Thrombosis

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Aetna considers AcuTect scintigraphic imaging for detection and localization of deep vein thrombosis (DVT) in the lower extremity experimental and investigational because the clinical value of this test in the management of persons with suspected DVT has not been clearly established by the peer-reviewed medical literature.

Background

Contrast venography (also known as contrast phlebography) is the gold standard for the diagnosis of DVT, although it is rarely used anymore because it is invasive, painful, time-consuming, and entails exposure to significant amounts of radiation. For patients with symptoms suggestive of DVT, compression ultrasonography is the most frequently used test. Pooled analyses showed that ultrasonography has a sensitivity of 96 % and a specificity of 98 % for proximal vein thrombosis. It has been reported that venous thromboembolic complications occur...
in less than 1 % of untreated patients in whom the presence of DVT is rejected on the basis of serial ultrasonography or ultrasonography plus either an assay for D-dimer (a fragment that is specific for the degradation of fibrin) or clinical score.

AcuTect (Diatide, Inc., Londenderry, NH) is a complex of a small-molecule synthetic peptide, acpitide, 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 to 60 minutes post-injection, administered by injection into the antecubital vein) imaging of DVT of the entire lower extremities, including the calf.

Information provided in the product labeling of AcuTect stated that the agreement rates between AcuTect and contrast venography are between 56 and 73 %. Furthermore, clinical follow-up studies of patients with negative AcuTect scans have not been carried out to determine if negative image findings represent the absence of acute venous thrombosis, and the rate of venous thromboembolic complications in untreated patients after a negative AcuTect scan has not been determined. Thus, the value of AcuTect in the management of patients with suspected DVT has not been clearly established.

Dunzinger et al (2008) studied the detection of acute DVT in patients presenting with clinical symptoms suggesting DVT and pulmonary embolism (PE) with (99m) Tc-acpitide. A total of 19 patients (11 males, 8 females) received within 24 hrs after admission to the hospital a mean of 841 MBq (range of 667 to 1,080) (99m)Tc-acpitide i.v. followed by planar recordings 10, 60, and 120 mins after injection. Images were compared to the results of compression ultrasonography and/or phlebography. Patients with clinically suspected PE underwent spiral computed tomography or lung perfusion scans. (99m)Tc-acpitide scintigraphy showed acute clot formation in 14 out of 16 patients where the other imaging modalities suggested DVT. Positive scintigraphic results were seen up to 17 days after the onset of clinical symptoms. In 3 out of 3 patients without any proof of DVT, (99m) Tc-acpitide scintigraphy was truly negative. Glycoprotein receptor imaging showed only one segmental PE in 6 patients with imaging-proven sub-segmental (n = 3) or segmental PE (n = 3). The authors concluded that (99m)Tc-acpitide scintigraphy
may be an easy and promising tool for the detection of acute clot formation in patients with DVT up to 17 days after the onset of clinical symptoms with a sensitivity of 87 % and a specificity of 100 %. However, it failed to demonstrate PE in 83 % of examined patients with proven PE.

Tan et al (2009) noted that currently the combination of a clinical decision rule, D-dimer testing and compression ultrasonography has proved to be safe and effective for the diagnosis of DVT in the lower extremities. Computed tomography (CT) and magnetic resonance imaging (MRI) can be useful as additional or secondary imaging modalities. Somarouthu and colleagues (2010) discussed the approach for diagnosing DVT in different patient populations. Clinical features and probability assessment guide further diagnostic tests. D-dimer testing is used as screening test; however, duplex ultrasound remains the primary confirmatory test. Furthermore, CT and MRI are used only in select patient populations (e.g., when ultrasound results are equivocal, in patients suspected of central venous DVT, or as a part of combined protocol for diagnosis of PE). The authors stated that contrast phlebography and plethysmography do not have much of a role during routine diagnosis of DVT.

Contrast venography (phlebography) is the "gold-standard" examination (Polak et al, 2005) for suspected deep venous thromboses of the lower extremity. An iodine-containing contrast agent is injected into a foot vein. DVT is present if a distinct filling defect is present in a deep vein of the calf or thigh. Other findings, such as an abrupt cutoff, absence of filling or presence of collaterals, are less specific and may be related to technical factors or to chronic venous thrombosis. American College of Radiology Appropriateness Criteria (Polak et al, 2005) on suspected lower extremity deep venous thrombosis state that invasive contrast phlebography may be necessary where other studies are equivocal or an intervention is planned. Contrast phlebography is assigned an appropriateness rating of 5 of 10. The authors note that, although this examination serves as the "gold standard", it may not give reliable results in 5 to 10 % of patients. It also carries some risks: contrast reaction, local irritation or skin loss due to extravasation, renal failure, and chemically induced thrombophlebitis.

Guidelines on venous thromboembolism from the University of Michigan (2009) state that phlebography "is seldom indicated any longer". The guidelines state that phlebography carries appreciable local morbidity, the risk of contrast administration, and is technically inadequate in 7 to 20 % of studies.
Ultrasound is recommended for patients with intermediate to high pretest probability of DVT in the lower extremities. Use of ultrasound in diagnosing symptomatic thrombosis in the proximal veins of the lower limb is recommended for patients whose pretest probability of disease falls in the category of intermediate to high risk of DVT under the Wells prediction rule. Ultrasound is less sensitive in patients who have DVT limited to the calf; therefore, a negative ultrasound does not rule out DVT in these patients. Repeat ultrasound or venography may be required for patients who have suspected calf-vein DVT and a negative ultrasound and for patients who have suspected proximal DVT and an ultrasound that is technically inadequate or equivocal. Contrast venography is still considered the definitive test to rule out the diagnosis of DVT.

### CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CPT codes not covered for indications listed in the CPB:</td>
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<tr>
<td>78456</td>
<td>Acute venous thrombosis imaging, peptide</td>
</tr>
<tr>
<td>75820</td>
<td>Venography, extremity, unilateral, radiological supervision and interpretation</td>
</tr>
<tr>
<td>75822</td>
<td>Venography, extremity, bilateral, radiological supervision and interpretation</td>
</tr>
<tr>
<td>78457</td>
<td>Venous thrombosis imaging, venogram; unilateral</td>
</tr>
<tr>
<td>78458</td>
<td>bilateral</td>
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<tr>
<td></td>
<td>ICD-10 codes not covered for indications listed in the CPB:</td>
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<tr>
<td>I80.10 - I80.13</td>
<td>Phlebitis and thrombophlebitis of femoral vein</td>
</tr>
<tr>
<td>I80.201 - I80.9</td>
<td>Phlebitis and thrombophlebitis of other and unspecified deep vessels of lower extremities</td>
</tr>
<tr>
<td>I82.0 - I82.91</td>
<td>Other venous embolism and thrombosis</td>
</tr>
<tr>
<td>O22.00 - O22.93</td>
<td>Venous complications in pregnancy</td>
</tr>
<tr>
<td>O87.0 - O87.9</td>
<td>Venous complications in the puerperium</td>
</tr>
<tr>
<td></td>
<td>Other HCPCS code related to the CPB:</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:

21. Grant B. Diagnosis of suspected deep venous thrombosis of the lower extremity. UpToDate [online serial]. Waltham, MA: UpToDate; updated February 8, 2010.
Amendment to
Aetna Clinical Policy Bulletin Number: 0414 AcuTect
Scintigraphic Imaging for Detection of Lower Limb Deep
Vein Thrombosis

There are no amendments for Medicaid.