

MEDICAL POLICY



SUBJECT: CT (COMPUTED TOMOGRAPHY) PERFUSION IMAGING OF THE BRAIN	EFFECTIVE DATE: 12/18/08 REVISED DATE: 12/17/09, 03/17/11, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 06/18/15, 02/18/16, 02/16/17, 02/15/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and review of the peer-reviewed literature, CT (computed tomography) perfusion imaging for assessing patients suspected of having an acute stroke or in triaging patients with stroke for interventional revascularization is considered **medically necessary**.
- II. Based upon our criteria and review of the peer-reviewed literature, CT (computed tomography) perfusion imaging has not been medically proven to be effective and is considered **investigational** for all other indications.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Perfusion imaging using CT is proposed to provide detailed study of cerebral blood flow that may assist in identification of ischemic regions of the brain, especially within the first few hours of an acute stroke. The technique requires either a diffusible inert gas indicator such as xenon (Xe) or a non-diffusible indicator such as an iodinated contrast agent. The CT scanner is then used to capture images as the agent accumulates in cerebral tissues. The technique tracks transient attenuation changes in the blood vessels and brain parenchyma during the first pass of an intravenously injected contrast medium. Results of CT perfusion studies allow calculation of regional cerebral blood volume (CBV), mean transit time (MTT), and regional cerebral blood flow (CBF). Proposed advantages of CT perfusion imaging are that it is less invasive than angiography and more widely available than MR imaging.

Three perfusion CT approaches use different data acquisition and analysis methods. *Whole brain CT perfused blood volume* is assessed by a helical scan through the whole brain with and without contrast. *First pass perfusion CT* (bolus tracking CT perfusion study) acquires repeated images at the same location through a volume of interest during bolus injection and passage of contrast through the region of interest. *Dynamic perfusion CT* acquires a temporal set of images through an extended volume of interest (imaging of tissue beyond the absolute width of the detector array) during a bolus injection of contrast.

RATIONALE:

Several post-processing software packages have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for use with a CT system to perform perfusion imaging, such as GE Medical Systems *CT Perfusion 4* (March 2006), Philips Medical systems *Brain Perfusion Option* (Feb. 2004) and Siemens Medical Solutions *syngo Perfusion-CT* (Dec. 2003).

The impact of CT perfusion imaging on health outcomes is not known. A non-contrast CT scan is regarded as the most important diagnostic tool in the assessment of patients with a suspected acute stroke to exclude hemorrhage and to demonstrate early infarct signs. CT perfusion imaging has been proposed as an additional technique that may provide information to differentiate patient subgroups that will be more likely to benefit from early reperfusion from those who

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are unlikely to benefit or may be harmed. While CT perfusion imaging may appear promising for improving care of patients with various neurological conditions, including the potential individualization of thrombolytic therapy in acute stroke, clinical trials are needed to demonstrate improvement in outcomes.

A number of retrospective studies and case series indicate that blood flow values obtained using a diffusible gas indicator are accurate and also that the flow rates correlate with physiological changes such as the onset of neurological deficits. However, prospective controlled studies have not been reported demonstrating that use of perfusion CT imaging improves outcomes in patients with acute stroke. Current studies primarily report results of imaging findings. How these findings relate to clinical outcomes, is not clear. CT perfusion imaging is also being evaluated in the management of other neurological conditions such as subarachnoid hemorrhage, epilepsy, head trauma and tumor.

The Agency for Healthcare Research and Quality (AHRQ) published a report on acute stroke in 2005. It addressed multiple issues regarding CT perfusion and also angiography in terms of how these modalities affect the use of thrombolytic therapy for acute ischemic stroke. The report indicated that studies with prospective use of CT perfusion and angiography techniques in patient selection for thrombolysis were not identified.

American Heart Association (AHA)/American Stroke Association (ASA)/American Academy of Neurology (AAN). Guidelines for Early Management of Adults with Ischemic Stroke (Jan 2013). Early Diagnosis, Brain and Vascular Imaging section states it is agreed that emergency, non-contrast-enhanced CT scanning of the brain accurately identifies most cases of intracranial hemorrhage and helps discriminate nonvascular causes of neurological symptoms, such as a brain tumor. The Early Diagnosis: Brain and Vascular Imaging section states that recent technological advances have led to increased interest in more sophisticated multimodal approaches to acute stroke imaging. Multimodal CT approaches may include noncontrast CT, perfusion CT, and CT angiography (CTA) studies. *Whole brain perfusion CT* provides a map of cerebral blood volume and it is postulated that regions of hypoattenuation on these cerebral blood volume maps represent the ischemic core. Although this technique has the advantage of providing whole-brain coverage, it is limited by its inability to provide measures of cerebral blood flow or mean transit time. *Dynamic perfusion CT* has the potential to provide absolute measures of cerebral blood flow, mean transit time, and cerebral blood volume. This technique is limited to 4 to 8 brain slices and provides incomplete visualization of all pertinent vascular territories, although newer (320-slice) CT machines can provide whole-brain coverage with this technique.

AHA/ASA concluded (multimodal CT section) these techniques have the advantage of relatively rapid data acquisition and can be performed with conventional CT equipment. Disadvantages include iodine contrast and additional radiation. The role of perfusion CT and CT angiography in making acute treatment decision has not yet been established.

AHA concluded that the usefulness of vascular imaging for predicting responses to treatment before intravenous administration of thrombolytic agents has not been demonstrated. AHA Class I recommendations state that multimodal CT and MR may provide additional information that will improve diagnosis of ischemic stroke. Class II recommendations state CT perfusion and MRI perfusion and diffusion imaging, including measures of infarct core and penumbra, may be considered for the selection of patients for acute reperfusion therapy beyond the time windows for intravenous fibrinolysis. These techniques provide additional information that may improve diagnosis, mechanism, and severity of ischemic stroke and allow more informed clinical decision making.

Recommendations from Imaging of Acute Ischemic Stroke: A Scientific Statement from the American Heart Association (2009) concluded that for patients beyond 3 hours from onset of symptoms, either Magnetic Resonance-Diffusion Weighted Imaging (MR-DWI) or CTA-SI should be performed along with vascular imaging and perfusion studies, particular if mechanic thrombectomy or intra-arterial thrombolytic therapy is contemplated (Class I, LOE: A).

Although current studies consist mainly of small case studies, there is growing evidence that perfusion imaging provides information on the volume of salvageable tissue to allow for treatment decisions beyond the three hour time window. As results of prospective randomized trials become more available, the indications for perfusion imaging of the acute stroke patients will likely increase.

American Heart Association (AHA) and American Stroke Association (ASA) 2012 guidelines for the management of aneurysmal subarachnoid hemorrhage recommend that perfusion imaging with CT or MR can be useful to identify

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regions of potential brain ischemia (Class IIa; Level of Evidence B). The guidelines state that there are emerging data that perfusion imaging, demonstrating regions of hypoperfusion, may be more accurate for identification of delayed cerebral ischemia than anatomic imaging of arterial narrowing or changes in blood flow velocity by transcranial Doppler. The guidelines concluded that CT perfusion is a promising technology, although repeat measurements are limited by the risks of dye load and radiation exposure.

American College of Radiology (ACR)/American Society of Neuroradiology (ASNR). An ACR/ASNR practice guideline (October 2012) for performance of CT perfusion in neuroradiologic imaging states that *brain primary indications* for perfusion CT in neuroradiology include, but are not limited to: acute neurological change suspicious for stroke, suspected vasospasm following subarachnoid hemorrhage, cerebral hemorrhage with secondary local ischemia, and intracranial tumors. *Brain secondary indications* are: follow-up of acute cerebral ischemia or infarction in the subacute or chronic phase of recovery, to assist in planning and evaluating effectiveness of therapy for arterial occlusive disease, and in patients with contraindication to magnetic resonance imaging (MRI) or with devices or material in or close to the field of view that would result in nondiagnostic MRI scans. Perfusion CT scanning may also be helpful in the setting of acute trauma. *Head and neck primary indications:* evaluation of the vascular status of solid tumors where MRI is degraded due to susceptibility artifact from air-containing spaces or from surgical clips or dental work. *Head and neck secondary indications:* follow-up of tumor response to therapy.

Perfusion CT in Brain Tumors

The current standard for tumor grading is a histopathologic assessment of tissue. Limitations of histologic assessment include sampling error due to regional heterogeneity and interobserver variation. These limitations can result in inaccurate classification and grading of gliomas. Because malignant brain tumors are characterized by neovascularity and increased angiogenic activity, perfusion imaging has been proposed as a method to assess tumor grade and prognosis. Dynamic contrast-enhanced MRI (DCE-MRI) is the preferred technique of choice because of no radiation exposure and a good signal-to-noise ratio. Perfusion CT may be an alternative choice for glioblastoma patients with DCE-MRI examination contraindications. Potential advantages, compared with magnetic resonance perfusion, include the wider availability, faster scanning times, and lower cost. CTP imaging may also be used to distinguish recurrent tumor from radiation necrosis.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 0042T Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral flood flow, cerebral blood volume, and mean transit time.

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HCPCS: No code

ICD10: I63.30-I63.9 Cerebral infarction (code range)

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KEY WORDS:

Dynamic Perfusion CT, Multimodal CT, PCT, Perfusion CT, Xenon-enhanced CT, XeCT.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for CT perfusion imaging.