



FEP Medical Policy Manual

FEP 6.01.49 Computed Tomography Perfusion Imaging of the Brain

Effective Policy Date: January 1, 2023

Original Policy Date: June 2012

Related Policies:

2.01.54 - Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Computed Tomography Perfusion Imaging of the Brain

Description

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Computed tomography perfusion (CTP) imaging provides an assessment of cerebral blood flow that may help identify ischemic regions of the brain. This technology is proposed to aid treatment decisions in patients being evaluated for acute ischemic stroke, subarachnoid hemorrhage (SAH), cerebral vasospasm, brain tumors, and head trauma.

OBJECTIVE

The objective of this evidence review is to determine whether the use of computed tomography perfusion imaging improves the net health outcome in individuals with acute stroke, subarachnoid hemorrhage, or brain tumors.

POLICY STATEMENT

Computed tomography perfusion imaging may be considered **medically necessary** to select individuals with anterior large-vessel stroke for mechanical embolectomy.

Computed tomography perfusion imaging of the brain is considered **investigational** for all other indications.

POLICY GUIDELINES

Selection criteria for the Extending the Time for Thrombolysis in Emergency Neurological Deficits - Intra-Arterial (EXTEND-IA) trial included participants with an anterior large-vessel stroke who: were receiving a tissue plasminogen activator; were able to receive endovascular therapy within 6 hours of stroke onset; were functionally independent prior to the stroke; and had evidence of salvageable brain tissue and an ischemic core with a volume of less than 70 mL on computed tomography perfusion imaging.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Several post-processing software packages (eg, Siemens' syngo Perfusion-CT, GE Healthcare's CT Perfusion 4, Philips Medical System's Brain Perfusion Option) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for use with a CT system to perform perfusion imaging. The software is being distributed with new CT scanners. FDA product code: JAK.

RATIONALE

Summary of Evidence

Acute Stroke

For individuals who have acute stroke who are being evaluated for thrombolysis who receive computed tomography perfusion (CTP) imaging, the evidence includes a systematic review with meta-analysis, a randomized controlled trial (RCT), and cohort studies. Relevant outcomes are overall survival (OS), test accuracy, symptoms, morbid events, and functional outcomes. One potential area of benefit is greater individualization of therapy for acute stroke by better defining at-risk ischemic areas that may benefit from thrombolysis. Evidence from nonrandomized comparative studies has suggested that outcomes after thrombolysis are better in patients who have target mismatch on perfusion imaging than in patients without target mismatch and that patients with target mismatch treated after a 3-hour time window have outcomes similar to patients treated within 3 hours. However, the therapeutic changes that would be associated with identifying specific target mismatch pattern on CTP are not well-defined. Additionally, although available evidence from the RCT suggests some modest benefit for acute stroke patients who receive CTP or magnetic resonance imaging and receive alteplase up to 9 hours post-stroke, the overall net health outcome is unclear because there was also a lack of significant benefit on the

secondary outcome of functional improvement and a trend toward increased risk of symptomatic intracranial hemorrhage. There were also important limitations in relevance and potential limitations in statistical power. Therefore, additional RCTs are needed to determine with greater certainty whether a strategy employing CTP imaging improves health outcomes compared with traditional strategies for the treatment of acute stroke. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have acute anterior large-vessel stroke who are being evaluated for mechanical embolectomy who receive CTP imaging, the evidence includes RCTs and cohort studies. Relevant outcomes are OS, test accuracy, symptoms, morbid events, and functional outcomes. Computed tomography perfusion is one of several approaches used in acute stroke to define viable ischemic tissue better and therefore identify patients who might benefit from mechanical endovascular intervention. Alternative methods of patient selection for mechanical embolectomy have included time from stroke onset, multiphase CTA, or Alberta Stroke Program Early CT Score. Three RCTs showed improved outcomes with mechanical embolectomy when patients were selected based on CTP results within 6 hours, at 6 to 16 hours, and at 6 to 24 hours. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have acute stroke who are being evaluated for prognosis who receive CTP imaging, the evidence includes retrospective analyses of large randomized trials. Relevant outcomes are OS, test accuracy, symptoms, morbid events, and functional outcomes. Retrospective analyses of data from the Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in The Netherlands (MR CLEAN) and the Dutch Acute Stroke Trial (DUST) studies have found that the ischemic core detected on CTP imaging was predictive of functional outcomes. However, analysis of data from the DUST study found no improvement in a prediction model when CTP imaging was added to a basic model that used only patient characteristics and non-contrast CT (NCCT). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Subarachnoid Hemorrhage

For individuals who have subarachnoid hemorrhage (SAH) and cerebral vasospasm who receive CTP imaging, the evidence includes a systematic review with meta-analysis and a cohort study. Relevant outcomes are OS, test accuracy, symptoms, morbid events, and functional outcomes. Computed tomography perfusion imaging is being evaluated for the diagnosis of vasospasm and delayed cerebral ischemia following aneurysmal SAH. One prospective study showed a qualitative measure of cerebral blood flow to have 93% accuracy for the detection of delayed cerebral ischemia, with lower accuracy for cerebral blood volume. Prospective trials are needed to determine whether CTP imaging in patients with aneurysmal SAH leads to the early identification of patients at high-risk for vasospasm or delayed cerebral ischemia, alters treatment decisions, and improves health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Brain Tumors

For individuals who have brain tumors who receive CTP imaging, the evidence includes studies on diagnostic accuracy. Relevant outcomes are test accuracy, symptoms, morbid events, and functional outcomes. The data on CTP imaging for brain tumors are limited. One study assessed the diagnostic accuracy of CTP imaging to differentiate high-grade from low-grade gliomas. Prospective studies in an appropriate population of patients are needed to evaluate the sensitivity and specificity of CTP glioma grading, with a histopathologic assessment of tumors as the independent reference standard. One prospective study performed a receiver operating characteristic curve analysis to evaluate the diagnostic accuracy of volume perfusion CT (VPCT). This is the first report using VPCT to differentiate gliomas; therefore, replication of these findings in an independent sample of patients is needed as well as clarification of the clinical utility of this information. Studies showing the consistency in the thresholds used are needed, as are studies showing improvement in health outcomes with CTP imaging. No recent reports on the use of CTP imaging for the evaluation of brain tumors have been identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in "Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association and American Stroke Association

The American Heart Association (AHA) and American Stroke Association (ASA; 2012) joint guidelines on the management of aneurysmal subarachnoid hemorrhage recommended that perfusion imaging with computed tomography or magnetic resonance can be useful to identify regions of potential brain ischemia (class IIa; level of evidence B).³⁷ The guidelines stated there are emerging data that perfusion imaging demonstrating regions of hypoperfusion may be more accurate for identifying delayed cerebral ischemia than anatomic imaging of arterial narrowing or changes in blood flow velocity by transcranial Doppler. The guidelines concluded that CTP imaging is a promising technology, although repeat measurements are limited by the risks of dye load and radiation exposure.

The AHA and ASA (2013) guidelines on the early management of adults with ischemic stroke recommended that CTP, magnetic resonance perfusion, and diffusion imaging, including measures of infarct core and penumbra, may be considered for selecting a patient for acute reperfusion therapy beyond intravenous fibrinolytic time windows.³⁸ The guidelines stated these techniques provide additional information that may improve diagnosis, mechanism, and severity of the ischemic stroke and permit more informed clinical decision making (class IIb, level of evidence B).

The AHA and ASA (2019) revised their 2018 guideline statement on the use of CTP for the early management of adults with ischemic stroke.³⁹ Table 1 summarizes the new recommendations that were made.

Table 1. AHA and ASA 2019 Guideline Recommendations on Use of CTP

Recommendation	SOR	LOB	LOE
In patients eligible for IV alteplase, because benefit of therapy is time dependent, treatment should be initiated as quickly as possible and not delayed for additional multimodal neuroimaging, such as CT and MRI perfusion imaging.	I	Strong benefit	B-NR (nonrandomized)
When selecting patients with acute ischemic stroke within 6 to 24 hours of last known normal who have large vessel occlusion in the anterior circulation, obtaining CTP or DW-MRI, with or without MRI perfusion, is recommended to aid in patient selection for mechanical thrombectomy, but only when patients meet other eligibility criteria from one of the RCTs that showed benefit from mechanical thrombectomy in this extended time window.	I	Strong benefit	A (high-quality evidence from multiple RCTs)
In selected patients with acute ischemic stroke (>16 to 24 hours of last normal) and large vessel occlusion, DAWN criteria (which may include imaging findings from CTP) may be used for clinical decision making regarding mechanical thrombectomy	IIa	Moderate benefit	B-R (nonrandomized)

AHA: American Heart Association; ASA: American Stroke Association; CT: computed tomography; CTP: computed tomography perfusion; DW-MRI: diffusion-weighted magnetic resonance imaging; IV: intravenous; LOB: level of benefit; LOE: level of evidence; MRI: magnetic resonance imaging; RCT; randomized controlled trial; SOR: strength of recommendation.

American Society of Neuroradiology et al

The American Society of Neuroradiology, the American College of Radiology (ACR), and the Society of NeuroInterventional Surgery (2013) issued a joint statement on imaging recommendations for acute stroke and transient ischemic attack.⁴⁰ The following statements were made on perfusion imaging:

- "In acute stroke patients who are candidates for endovascular therapy, vascular imaging (CTA [computed tomography angiography], MRA [magnetic resonance angiography], DSA [digital subtraction angiography]) is strongly recommended during the initial imaging evaluation. Perfusion imaging may be considered to assess the target tissue 'at risk' for reperfusion therapy. However, the accuracy and usefulness of perfusion imaging to identify and differentiate viable tissue have not been well-established."

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- "Determination of tissue viability based on imaging has the potential to individualize thrombolytic therapy and extend the therapeutic time window for some acute stroke patients. Although perfusion imaging has been incorporated into acute stroke imaging algorithms at some institutions, its clinical utility has not been proved."
- "It is important to note that perfusion imaging has many applications beyond characterization of the penumbra and triage of patients to acute revascularization therapy.... These applications include, but are not limited to, the following: 1) improving the sensitivity and accuracy of stroke diagnosis (in some cases, a lesion on PCT [perfusion-computed tomography] leads to more careful scrutiny and identification of a vascular occlusion that was not evident prospectively, particularly in the M2 and more distal MCA [middle cerebral artery] branches); 2) excluding stroke mimics; 3) better assessment of the ischemic core and collateral flow; and 4) prediction of hemorrhagic transformation and malignant edema."

The American Society of Neuroradiology, the Society for Pediatric Radiology, and ACR (2017) revised their joint practice parameters on the performance of CTP in neuroradiologic imaging.⁴¹ The primary indications for CTP imaging of the brain were described as acute neurologic change suspicious for stroke, suspected vasospasm following subarachnoid hemorrhage, and cerebral hemorrhage with secondary local ischemia. Secondary indications included follow-up of acute cerebral ischemia or infarction, to assist in planning and evaluating therapy effectiveness, in patients with a contraindication to magnetic resonance imaging, in the setting of acute traumatic brain injury, and intracranial tumors. There was "little data" to support the role of brain CTP imaging in pediatric stroke.

American College of Radiology

The ACR Appropriateness Criteria, updated in 2016, have provided the following ratings for head CTP imaging with contrast (see Table 2).⁴²

Table 2. Appropriateness of Head CTP Imaging With Contrast

Recommendation	Rating
For asymptomatic individuals with a structural lesion on physical examination (cervical bruit) and/or risk factors	5
If directly employed in decision making and planning treatment for carotid territory or vertebrobasilar transient ischemic attack on the initial screening survey	5
For a new focal neurologic defect, fixed or worsening; less than 6 hours	6
For a new focal neurologic defect, fixed or worsening; longer than 6 hours	5
For evaluation for cerebral vasospasm after aneurysmal subarachnoid hemorrhage	5

Rating scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate.

CTP: computed tomography perfusion.

The ACR also noted that computed tomography stroke protocols combining a brain noncontrast computed tomography, computed tomography angiography, and CTP might produce a relative radiation level of 1 to 10 mSv, and repeated use of this protocol in an individual patient might result in high radiation exposure to the scalp and eyes.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	Replace policy	
March 2013	Replace policy	Policy updated with literature search, references added and reordered, policy statement unchanged
December 2013	Replace policy	Policy updated with literature search through July 17, 2013; reference 16 added; €œof the Brain€ added to title and policy statement for clarification.
December 2014	Replace policy	Policy updated with literature review adding references 18, 25, 27, and 28. The policy statement is unchanged.
December 2015	Replace policy	Policy updated with TEC Assessment (reference 1). CT perfusion considered medically necessary in patients with anterior large-vessel stroke being evaluated for mechanical embolectomy. CT perfusion in other situations remains not medically necessary

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Date	Action	Description
December 2016	Replace policy	Policy updated with literature review; references 3, 6, 15, 18, and 30 added; reference 31 updated. The TEC Assessment was not published and has been removed from the reference list. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through July 20, 2017; references 4, 18, 20, and 31 added. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through August 9, 2018; reference 27 added; reference 29 updated. Policy statements unchanged. Policy archived.
December 2020	Replace policy	Policy reactivated with updated with literature review through July 21, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through July 27, 2021; reference added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through July 19, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.

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