Local Coverage Determination (LCD): Computed Tomography Cerebral Perfusion Analysis (CTP) (L38667)

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CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Section 1862 (a)(7) excludes routine physical examinations.

CMS Publications:

CMS Publication 100-3, *National Coverage Determination Manual*, Chapter 1
220.1 Computerized Tomography

CMS Publication 100-4, *Medicare Claims Processing Manual*, Chapter 13
20 Payment Conditions for Radiology Services

CMS Publication 100-9, *Contractor Beneficiary and Provider Communication Manual*, Chapter 5
20 Correct Coding Initiative

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

CTP (using automated post-processing software algorithmic analysis) is medically reasonable and necessary in patients with small acute ischemic stroke (AIS) caused by a unilateral large vessel occlusion (LVO) in the proximal anterior circulation evaluated at stroke centers; CTP can be used to aid in selection for endovascular mechanical thrombectomy (EVT) if one of the following other conditions is fulfilled:

1. Treatment (femoral puncture) can be started within **6-24 hours** of the time last known to be at neurologic baseline and who meet the pre-CTP inclusion/exclusion criteria* as defined by the DAWN trial (1), or
2. Treatment (femoral puncture) can be started within **6-16 hours** of the time last known to be at neurologic baseline and who meet the pre-CTP inclusion/exclusion criteria* as defined by the DEFUSE 3 trial (2)

*excluding criteria purely related to study mechanics (e.g., able to return for protocol required follow-up visits, etc.).

Summary of Evidence

Noncontrast CT (NCCT) is the mainstay for initial AIS imaging due to widespread availability, rapid scan times, and detection of intracranial hemorrhage (which leads to very different management from infarction). Multimodal CT includes NCCT, CT angiography (CTA) (to assess site of vascular occlusion), and CT Perfusion Imaging (CTP). CTP consists of a temporal sequence of head CT scans obtained during the wash-in and wash-out of an IV bolus of iodinated contrast agent. Post-acquisition data analysis by dedicated software allows creation of multiple hemodynamic parametric maps (based on contrast time-density curves) for clinical interpretation. Hemodynamic parameters include time to maximum contrast intensity (Tmax), mean transit time (MTT), cerebral blood flow (CBF) and cerebral blood volume (CBV), mathematically related by the equation CBF = CBV/MTT (3). These maps are able to estimate brain regions with high probability of irreversible infarction (ischemic core) versus areas of potentially reversible ischemia (penumbra). Both core and penumbra are estimates of probabilistic tissue fate. While CTP has been studied in acute ischemic stroke for decades (4), only recently was it found likely to influence treatment decision (5). Subsequently, two level I randomized controlled trials (RCTs) (DAWN and DEFUSE 3) found CTP helped determine eligibility for EVT in the late time period (6-24 hr.) of an acute (<24 hr.) ischemic stroke (AIS) (1,2), a paradigm shift away from confinement to the early window (< 6 hr.).

The DAWN trial (Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention With Trevo) studied whether patients with a clinical deficit that is disproportionately severe relative to the infarct volume may benefit from late EVT (1). See table for key inclusion criteria. Patients were randomly assigned to EVT plus standard medical management (MM) (N=107, mean age 69.4 yr.) or to MM alone (N=99, mean age 70.7 yr.). Median National Institutes of Health Stroke Scale (NIHSS) score was 17 (moderate to

severe stroke) for both groups. The trial was stopped for efficacy at the first interim analysis. At 90 days, the rate of functional independence, as defined by a score of 0-2 on the modified Rankin scale (mRS) of 0-6, was greater for EVT than MM (49% versus 13%; adjusted difference, 33%; 95% CI, 21–44; posterior probability of superiority >0.999). The rate of symptomatic intracranial hemorrhage did not differ significantly between the two groups (6% in the EVT group and 3% in the MM group, P=0.50), nor did 90-day mortality (19% and 18%, respectively; P=1.00).

Key Inclusion Criteria for DAWN and DIFUSE 3

Parameter	DAWN	DEFUSE 3
Prestroke baseline mRS (0-6)	mRS ≤1 (no significant disability)	mRS ≤2 (slight disability)
Last known well to treatment time	6-24 h	6-16 h
Minimum NIHSS score (0-42)	10 (moderate stroke)	6 (moderate stroke)
LVO by MR or CT angiography	ICA (intracranial) and/or M1 segment of MCA	ICA (cervical or intracranial) and/or M1 segment of MCA
Clinical-core mismatch (core volume based on a relative CBF threshold of <30% of normally perfused tissue)	≤20 mL if age ≥80 ≤30 mL if age <80 and NIHSS 10–20 ≤50 mL if age <80 and NIHSS >20	≤70 mL and NIHSS ≥6
Penumbra-core volume mismatch	not required	penumbra volume ≥15 mL (Tmax >6 s volume minus core volume) and a penumbra to core ratio of ≥1.8

mRS, modified Rankin score; NIHSS, National Institutes of Health Stroke Scale; LVO, large anterior vessel occlusion; ICA, internal carotid artery; M1/MCA, first segment of the middle cerebral artery; CBF, cerebral blood flow; Tmax, time from contrast injection to maximum intensity.

The DEFUSE 3 trial (Diffusion and Perfusion Imaging Evaluation for Understanding Stroke Evolution) was a multicenter, randomized, open-label trial that used perfusion-core mismatch and maximum core size as imaging criteria to select patients for late EVT (2). See table for key inclusion criteria. Patients were randomly assigned to EVT plus standard MM or standard MM alone. The trial was conducted at 38 U.S. centers and terminated early for efficacy after 182 patients had undergone randomization (EVT N=92, median age 70; MM N=90, median age 71). Median NIHSS score was 16 (moderate to severe stroke) for both groups. The EVT group showed a benefit in functional outcome at 90 days (mRS score 0–2, 44.6% versus 16.7%; RR, 2.67; 95% CI, 1.60–4.48; P<0.0001). The 90-day mortality rate trended in favor of EVT (14% vs. 26% (P=0.05)), and there was no significant difference between groups in the rate of symptomatic intracranial hemorrhage (7% and 4%) or of serious adverse events (43% and 53%). In a subgroup analysis, both the favorable outcome rate and treatment effect did not decline in transfer patients compared to direct-admission patients (6).

The DAWN and DEFUSE 3 trials differed in their approach in identifying salvageable brain (table). The DAWN trial selected patients based on a clinical-core mismatch, whereas the DEFUSE 3 trial focused on a penumbra-core mismatch. Both target the same conceptual goal, identifying patients with enough salvageable, at risk, tissue to warrant EVT risks. In both cases, brain tissue was designated as having irreversible injury if CBF was less than 30% of that seen in contralateral perfused tissue by CTP (or less commonly, magnetic resonance MR (MR) perfusion-weighted imaging (MR-PWI)) as detected by RAPID automated perfusion post-processing software. Both trials demonstrated a large clinical benefit, with numbers needed to treat (NNT) of 3-4 to prevent functional dependence. There were differences in protocol as well. DAWN excluded patients with an infarct involving more than one third of the territory of the MCA at baseline. DEFUSE-3 enrolled patients with lower NIHSS score (less clinical severity), larger core infarct, and slightly higher baseline mRS disability score. One third of DAWN-eligible patients are DEFUSE-3 ineligible. Epidemiologic data suggest that about one-third of AIS patients present between 6-24 hours, and only 9.2% of these (or 2.7% overall) meet DAWN or DIFFUSE 3 inclusion criteria (7,8). Of all patients with acute ischemic stroke presenting to a single comprehensive stroke center, 1.7% of patients qualified for DAWN clinical trial enrollment with an additional 0.6-1% qualifying for the DEFUSE-3 trial (7).

Both studies employed CTP or MR-PWI to select patients for EVT, with CTP predominating. DEFUSE 3 subgroup analysis showed no statistical difference in treatment effect between "patients selected on the basis of diffusion/perfusion MRI and those selected on the basis of CT perfusion imaging," though the authors admit statistical power was limited by the lower number of patients enrolled as a result of early termination. DAWN subgroup analysis did not include comparison by qualifying image method. One criticism of both studies was the large number of "wake-up strokes" (~50%) vs. 14-28% in the general population, perhaps contributing to overestimation of stroke age, and therefore, better outcomes (9,10). The authors note that a higher proportion of unwitnessed strokes are expected in trials enrolling patients late after onset, as witnessed strokes are typically treated early, and that the benefit persisted even after stratification into witnessed and unwitnessed stroke groups (11,12). They also explain that outcomes were "paradoxically" superior to early window (< 6 hr.) treatment trials, probably due to selection for a large volume of penumbral (i.e., salvageable) tissue.

A subsequent prospective review (13) and retrospective registry (14) analysis also support the value of CTP in late period EVT eligibility assessment, while also emphasizing the need to correlate perfusion abnormalities with other imaging (NCCT, CTA) and clinical information; they may be more sensitive than CTP for detecting irreversibly damaged tissue as time progresses. For example, CTP may show increased CBF over time due to collaterals to tissue already irreversibly injured (15). Also stressed is the need for more standardization of CTP vendor software and post-processing techniques to decrease variation in calculated core and mismatch (3,15). However, even with fully automated software, a significant clinician interpretation learning curve remains (16).

Non-AIS indications

One non-ischemic stroke CTP potential use is in determining delayed cerebral ischemia (DCI), occurring in approximately 30% of patients within two weeks after aneurysmal subarachnoid hemorrhage (SAH) (17). The most common etiology of DCI is thought to be vasospasm produced by spasmogenic substances generated during lysis of subarachnoid blood. Monitoring for DCI can be done with CTA to confirm vasospasm in patients with elevated velocities on transcranial Doppler (TCD) ultrasound (17). However, brain perfusion asymmetry on CTP has been studied for this purpose as well. A 2014 systematic review and meta-analysis (18), included four small observational studies of 188 patients (19-22). The weighted averages and ranges of the pooled sensitivity and specificity of CTP in the determination of DCI were 0.84 (0.7-0.95) and 0.77 (0.66-0.82), respectively. The pooled odds ratio was 23.14 (95% CI, 5.87-91.19). The authors conclude that "perfusion deficits on CTP may be helpful in identifying patients with delayed DCI before development of infarction and neurologic deficits." However, they also cite many definitional and methodology limitations of the underlying studies (nonuniform DCI definition as an outcome measure, CTP protocol and postprocessing software differences, lack of consistency of what constitutes an abnormal CTP test result, optimal time to perform CTP, and nonstandard hemodynamic parameter thresholds). In addition, accurate

quantification is dependent on an intact blood-brain barrier, which may not be functioning in DCI.

Small cohort studies have explored the potential role of CTP for patients with traumatic brain injury (TBI). A small study of 48 patients reported NCCT had sensitivity of 39.6% compared to improved sensitivity of CTP of 87.5% for cerebral contusions diagnosed on delayed follow-up imaging (23). Additional studies suggest reductions in blood flow and volumes determined by CTP are associated with worse outcome (24). A subset analysis of 30 patients from an observational study reported the information obtained from CTP is useful in decision making (25).

CTP has been proposed as a possible modality for non-invasive assessment of brain tumors. Several small (<20 patient), retrospective reports showed promising early results in diagnosing malignant verses normal tissue, evaluating for metastatic disease, and differentiating tissue type in brain tumors (26,27). A small prospective trial of 49 consecutive patients with brain tumors or tumor-like lesions were evaluated with CT and CTP. The results suggest CTP can aid in distinguishing glioma and lymphomas based on quantitative measurements of CBV and permeability (28). The reports indicate need for further investigation of cut-off values, accuracy and patient selection criteria, to determine if clinically useful.

Analysis of Evidence
(Rationale for Determination)

The 2019 update to the 2018 American Heart Association (AHA)/American Stroke Association (ASA) guidelines for the early management of patients with AIS state: "When selecting patients with AIS within 6 to 24 hours of last known normal who have LVO in the anterior circulation, obtaining CTP, 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" (Class of recommendation I-strong; level (quality) of evidence A) (29). Since only the DAWN and DEFUSE 3 RCTs show a benefit of late period EVT, they further warn: "DAWN or DEFUSE 3 eligibility should be strictly adhered to in clinical practice." These guidelines do not recommend CTP to determine eligibility for either thrombolytic therapy or EVT in the early (<6 hour) period (Class of recommendation I-strong; level (quality) of evidence B-Nonrandomized), or for any other indication (e.g., prediction of hemorrhagic transformation (HT) in acute ischemic injury). Other guidelines have similar recommendations (30-32). National Institute for Health and Care Excellence (NICE) recommends: "Add CT perfusion imaging (or MR equivalent) if thrombectomy might be indicated beyond 6 hours of symptom onset" (33). This recommendation uniquely also includes posterior circulation stroke. However, there is minimal evidence regarding the appropriate threshold and utility of CTP in the posterior circulation, and MRI is a better alternative (3).

The 2017 American College of Radiology (ACR)-American Society of Neuroradiology (ASNR)-Society of Pediatric Radiology (SPR) guidelines lists primary and secondary indications for CTP in neuroradiology, including evaluation of AIS, neoplasia, trauma, cerebral hemorrhage, and vasospasm following subarachnoid hemorrhage (34). The 2012 AHA/ASA guidelines for the management of aneurysmal SAH state that "perfusion imaging with CT or magnetic resonance can be useful to identify regions of potential brain ischemia" (Class IIa; Level of Evidence B) (35). However, current UpToDate guidance concludes that CTP "clinical utility…..remains to be established" and that "the use of this technique as a monitoring tool may be limited by risks of recurrent dye loads and radiation exposure" (17), as well as by lack of standardized methodology (18). The 2015 AHA/ASA guidelines for the management of spontaneous intracerebral hemorrhage has no mention of CTP (36), nor does UpToDate (37). Regarding trauma and oncologic indications, there appears to be insufficient evidence to support routine use of CTP.

In summary, we consider the concordant level I evidence of a large clinical benefit after CTP imaging (using

automated post-processing software algorithmic analysis) in AIS secondary to LVO, to assist in late EVT eligibility determination per AHA/ASA guidelines, medically reasonable and necessary. Other stroke or non-stroke indications lack level I evidence and are not considered medically reasonable and necessary at this time.

General Information

Associated Information

N/A

Sources of Information

N/A

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Associated Documents

Attachments

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Related Local Coverage Documents

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A58152 - Billing and Coding: Computed Tomography Cerebral Perfusion Analysis (CTP)
A58327 - Response to Comments: Computed Tomography Cerebral Perfusion Analysis (CTP)

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