Local Coverage Determination (LCD)

LCD - Category III Codes (L35490)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alabama Alaska Arizona Arkansas California - Entire State Colorado Connecticut Delaware Florida Georgia Hawaii Idaho Illinois Indiana Iowa Kansas

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
				Kentucky Louisiana Maine Maryland Massachusetts Michigan Mississippi Missouri - Entire State Montana Nebraska Nevada New Hampshire New Jersey New Mexico North Carolina North Dakota Ohio Oklahoma Oregon Pennsylvania Rhode Island South Carolina South Dakota Tennessee Texas Utah Vermont Virginia Washington West Virginia Wisconsin Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

LCD Information

Document Information

LCD ID
L35490

LCD Title
Category III Codes

Proposed LCD in Comment Period
N/A

Source Proposed LCD
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For services performed on or after 10/01/2015

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N/A

Notice Period Start Date
04/28/2022

Notice Period End Date
06/11/2022

Issue

Issue Description

Biannual review completed. Updates made to AMA format throughout document. Under **Utilization Guidelines** all references to CPT code 0275T were removed as these are covered in NCD 150.13.

CMS National Coverage Policy

Social Security Acts

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

- Title XVIII of the Social Security Act, Section 1833(e) of the Social Security Act prevents Medicare from paying for services unless necessary and sufficient information is submitted that shows that services were provided and to determine the amounts due
- Title XVIII of the Social Security Act Section 1862(a)(1)(D) refers to limitations on items or devices that are investigational or experimental.

CMS IOM Citations

- CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14- Medical Devices, § 10, Coverage of Medical Devices.
- CMS IOM Publication 100-03 Medicare Benefit Policy Manual, Chapter 1, Part 1, § 20.4 Implantable Automatic Defibrillators.
- CMS IOM Publication 100-03 Medicare Benefit Policy Manual, Chapter 1, Part 2, § 150.13 Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS); and Part 4, § 310 Clinical Trials.
- CMS IOM Publication 100-04, Medicare Benefit Policy Manual, Chapter 23- Fee Schedule Administration and Coding Requirements, § 30 Services paid under the Medicare Physicians Fee Schedule.
- CMS IOM Publication 100-04 Claims Processing Manual, Chapter 32, § 68 Investigational Device Exemptions (IDE) Studies, and § 330 Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS).
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 13, § 13.5.4 Reasonable and necessary provisions in LCDs & § 13.5.3 Evidentiary Content
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 13, § 13.2.4- Proposed LCD.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

The American Medical Association (AMA) develops temporary Current Procedural Terminology (CPT) Category III codes to track the utilization of emerging technologies, services, and procedures. The CATEGORY III CPT Code description does not establish a service or procedure as safe, effective or applicable to the clinical practice of medicine.

Indications and Limitations:
Section 1862(a)(1)(A) of the Social Security Act (SSA) is the statutory basis for denying payment for types of care, items, services, and procedures, not excluded by any other statutory clause while meeting all technical requirements for coverage, that are determined to be any of the following:

1. Not generally accepted by the medical community as safe and effective in the setting and for the condition for which it is used;
2. Not proven safe and effective based on peer review or scientific literature;
3. Experimental;
4. Not medically necessary for a particular patient;
5. Furnished at a level, duration, or frequency that is not medically appropriate;
6. Not furnished in accordance with accepted standards of medical practice; or
7. Not furnished in a setting appropriate to the patient’s medical needs and condition.

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:

1. Consistent with the symptoms of diagnosis of the illness or injury under treatment; **and**
2. Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not experimental) **and**;
3. Not furnished primarily for the convenience of the patient, the provider or supplier; **and**
4. Furnished at the most appropriate level of care that can be provided safely and effectively to the patient.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational and are not considered reasonable and necessary under SSA 1862(a)(1)(A). Medicare payment, therefore, may not be made for procedures performed using devices that have not been approved for marketing by the FDA unless performed within the context of a clinical trial qualifying under the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) or in approved FDA Investigational Device Exemption (IDE) trial.

A/B MACs (B) continue to determine if a service is reasonable and necessary to treat illness or injury. If a service is not reasonable and necessary to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), A/B MACs (B) consider the service noncovered notwithstanding the presence of a payment amount for the service in the Medicare fee schedule.

FDA designation/ determination of a device as 510(k) mean(s) that the device has been approved for marketing by the FDA because it is similar to something already on the market that was "grandfathered in" by the FDA and therefore these devices are eligible for coverage.

In addition, items, services, or devices may also be not covered under SSA 1862(a)(1)(D), (E), or (O).

Summary of Evidence

Coverage Determinations according to IOM 100-04 Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations and Change Request 10901, effective 01/08/2019, are listed below.

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

Computed Tomographic Perfusion (CTP) (using automated post-processing software algorithmic analysis) is medically reasonable and necessary in patients with acute ischemic stroke (AIS) caused by unilateral large vessel occlusion (LVO) in the proximal anterior circulation evaluated at stroke centers, to aid in selection for endovascular mechanical thrombectomy (EVT) if all of the following conditions are fulfilled:

1. Intracranial internal carotid artery (ICA) **OR** middle cerebral artery (MCA) occlusion
2. The medical record documents the patient is being considered for endovascular mechanical thrombectomy (EVT) and does not have contraindications to the EVT (based on DAWN or DEFUSE3 trial criteria)
3. Treatment (femoral puncture) can be started within 6-24 hours of the last time known to be at neurologic baseline

Computed Tomographic Perfusion (CTP) accuracy: A 2020 systematic review aimed to evaluate the diagnostic accuracy of CTP in the prediction of hemorrhagic transformation and patient outcome in AIS reported CTP sensitivity as 85.9%, specificity of 73.9%, positive predictive value 60.3% and negative predictive value of 92.9%.[11] A 2017 systematic review identified 27 studies with a total of 2168 patients. The pooled sensitivity of CTP for acute ischemic stroke was 82% (95% CI 75–88%), and the specificity was 96% (95% CI 89–99%). They determined CTP was more sensitive than Non-contrast Computerized Tomography (NCCT) and had a similar accuracy with Computed

tomography angiography (CTA), but also that the evidence was not strong, and there is a need for high-quality evidence to confirm results.[18] Older systematic reviews report mixed results with a wide range in sensitivity and specificity of CTP for detection of acute ischemic stroke (AIS).[18] A 2019 systematic review and meta-analysis comparing imaging modalities for evaluation of AIS concludes that while CTP was more accurate than NCCT for detection of AIS, it was less accurate than diffusion-weighted imaging (DWI) magnetic resonance imaging (MRI) (sensitivity 82%, specificity 96% vs. sensitivity 15-86%, specificity 100%, respectively).[19] DWI is considered the gold standard for imaging diagnosis of acute ischemia and more accurate than NCCT, CTA, and CTP to estimate or infer the size of core and penumbra.[20] However, NCCT is considered the current standard for stoke evaluation as MRI use in emergency settings may be limited, as well as several contradictions for MRI.[21] Most studies evaluated in these systematic reviews were retrospective with variability in inclusion and exclusion criteria, outcomes reported, and sampling procedures, which introduces a high risk for bias, heterogenicity, and overall reduced quality of evidence. The evidence for routine use of CTP for evaluation for AIS is low quality and there is a need for high-quality evidence to determine the role it may play in AIS evaluation.

Hemorrhagic transformation (HT) zone: 2020 systematic review reported prediction of the HT could guide decision making in regard to consideration at thrombolysis decision point and concludes CTP is a useful prognostic tool for clinicians at the point of intervention decision making for AIS.[11] This review, however, consisting of 3 prospective and 9 retrospective studies, is subject to inaccuracy given the risk of bias and a high degree of heterogenicity in the selected studies. Another small retrospective study with 46 patients who received recanalization therapy also concluded usefulness in CTP as a predictor of HT.[22] On the contrary, a large prospective trial with 545 patients treated with IV tPA or thrombectomy had CTP at admission, and day 3 follow-up looked at the ability of the technology to predict HT (by measurement of the blood brain barrier permeability (BBBP). While univariate analysis associated BBBP measured by CTP as an independent predictor of HT, the multivariant analysis did not reproduce those findings, and the addition of BBBP as a variable did not change the AUC (0.77, 95% CI 0.71–0.83) of the model. The authors concluded BBBP measured by CTP did not improve prediction of HT, and improvements are needed before being considered "a useful addition to decision making".[23] At this point, there are mixed results, lack of high-quality data, and lack of standardized scoring to determine treatment threshold to support the use of CTP for prediction of HT zone.

Evaluation for Endovascular mechanical thrombectomy (EVT): There are 2 level I randomized controlled trials (RCTs), which both conclude CTP is useful in determining eligibility for EVT in the late time period (6-24 hr.) of an acute (<24 hr.) ischemic stroke (AIS). The DAWN trial (DWI or CTP Assessment with 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.[8] Their protocol included stringent inclusion and exclusion criteria. All patients had evidence of occlusion in internal carotid artery (ICA) with computed tomography (CT) or MRI imaging with CTP or DWI to determine infarct volume. 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).

The DEFUSE 3 trial (Diffusion and Perfusion Imaging Evaluation for Understanding Stroke Evolution) was a multicenter, randomized, open-label trial randomizing patient with occlusion in the ICA or middle cerebral artery (MCA) based on computed tomography angiography (CTA) or magnetic resonance angiogram (MRA). Perfusion study with CTP or MRI diffusion was used to determine perfusion-core mismatch and maximum core size as imaging criteria to select patients for late EVT.[3] 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). The 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 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.[24]

Both trials were designed to assess the effectiveness of EVT within 6-24 hours, but also provided evidence on the utility of CTP for aiding in management decisions. A subsequent prospective review[25] and retrospective registry[26] analysis also support the value of CTP in late period EVT eligibility assessment.

While DWI is considered the gold standard, CTP has the advantage of more availability, faster acquisition, and a similar estimate of mismatch, therefore becoming the dominant advanced imaging tool for identifying the core and penumbra.[20] CTP was used as an acceptable modality for triage for EVT in both the DAWN and DEFUSE3 studies and appear to be useful in aiding patient selection for thrombectomy (risk ratio for functional independence at day 90 was CPT 2.50, 95%CI: 1.32 to 4.75 and MRI 3.17, 95%CI: 1.35 to 7.43).[21,27] Results, however, must still be interpreted with caution. A 2020 retrospective study that evaluated patients undergoing CTP for EVT triage included 176 consecutive patients undergoing CTP and CTA. Automated calculations were performed with proprietary software, and failures were reprocessed manually. The primary outcome was postprocessing failure, defined as the presence of perfusion abnormalities caused by artifact and verified on follow-up images, and was reported in 11% of cases (20/176). Causes included severe motion, streak artifact, and poor arrival of contrast. Half of the failures (n=6) led to erroneous ischemic core volumes that may have resulted in different treatment decisions if the CTP results had not been corrected. The authors conclude that results from automated CPT should be interpreted with caution, and failures should be recognized and corrected to ensure appropriate management decisions are made.[28] In most cases, the key to improved diagnostic certainty is to interpret the CTP, not in isolation, but in conjunction with the NCCT, CTA, NIHSS, and clinical history.[20]

0525T-0532T

0525T Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)
0526T Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only
0527T Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only
0528T Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report
0529T Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report
0530T Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)
0531T Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; electrode only
0532T Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; implantable monitor only.

Holmes et al.: The randomization technique is not described. The sample size is not justified. The investigation is for 6 months with an additional 6-month follow-up. The authors state that more work is needed to understand the false positive and false negative rates and the actual clinical benefit; these are important issues in determining coverage.

Gibson et al.: The randomization technique is not described. The authors state, "Although the trial did not meet its

pre-specified primary efficacy endpoint, results *suggest…"* Obviously, this is too preliminary to support coverage.

Fischell et al.: This is a non-randomized feasibility study.

Correspondence: Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance are not sufficient evidence of general acceptance by the medical community.

Summary of Safety and Effectiveness Data: Is not able to be utilized to support coverage.

User's Guide, Manual, and Programming Guide: Is not able to be utilized to support coverage.

ACC/AHA Guidelines: These are not germane to the issue of coverage of a specific device, and is not current information, dated 2004.

Mirzaei et al.: This reviewer did not see the relevance of this article related to your request.

DeVon et al.: This article describes a weak selection methodology and seems directed to providing guidance for nursing education of patients. This reviewer did not see the relevance to coverage of a specific device.

Sheifer et al.: This article does not seem to address the issue at hand and is not current information, dated 2001.

Flynn et al.: This case series does not seem to address the issue at hand related to your request.

Gersch et al.: This article does not address the issue at hand related to your request.

Kwong et al. with correction: Case series apparently not germane to question at hand related to your request.

Moser et al.: Consensus statement that does not address the issue at hand related to your request.

Sanchez et al.: This case-control can be used to generate hypotheses for further study, but it cannot address the issue at hand.

Wasson et al.: This is an investigation of the quality of life burden of post-traumatic stress disorder due to acute coronary syndrome. This reviewer does not see its relevance to the issue at hand.

0398T

<u>MRgFUS unilateral thalamotomy is considered medically reasonable and necessary in patient with one of the following:</u>

1. Essential Tremor (ET)- defined as refractory to at least 2 trials of medical therapy, including at least 1 first-line agent
2. Tremor-Dominant Parkinson's disease (TDPD) (and both a & b)
    a. refractory (or intolerant) to levodopa or levodopa equivalent daily dosage (LEDD) ≥ 900 mg

b. On-medication Unified Parkinson's Disease Rating Scale (UPDRS) ratio of the mean score for tremor items (items 16, 20, and 21) to the mean postural instability/gait disorder score (items 13-15, 29, and 30) of ≥ 1.5

And all of the following:

- Moderate to severe postural or intention tremor of the dominant hand (defined by a score of ≥2 on the Clinical Rating Scale for Tremor (CRST)
- Disabling tremor (defined by a score of ≥2 on any of the 8 items in the disability subsection of the CRST
- Not a surgical candidate for deep-brain stimulation (DBS) (e.g., advanced age, anticoagulant therapy, or surgical comorbidities

Exclusion from Coverage:

1. Treatment of head or voice tremor
2. Bilateral thalamotomy
3. Following conditions:
    a. A neurodegenerative condition other than Parkinson's disease
    b. Unstable cardiac disease
    c. Untreated coagulopathy
    d. Risk factors for deep-vein thrombosis
    e. Severe depression, i.e., a score greater than or equal to 20 on the Patient Health Questionnaire 9 (PHQ-9)
    f. Cognitive impairment defined by a score of less than 24 on the Mini-Mental Status Examination
    g. Previous brain procedure (transcranial magnetic stimulation, deep brain stimulation, stereotactic lesioning, or electroconvulsive therapy)
    h. A skull density ratio (the ratio of cortical to cancellous bone) of <0.45 ± 0.05 as calculated from the screening CT.
    i. MRI contraindication
    j. Drug-induced Parkinsonism
    k. History of seizures, brain tumor, intracranial aneurysm or arteriovenous malformation requiring treatment
    l. pregnancy

<u>Essential tremor (ET)</u>
Elias, JW, Lipsman N, Ondo WG,et al conducted a randomized clinical trial with masked assessment and recognized outcome parameter with a 1 year follow up.[2] There is a relatively high adverse event rate, but it is a relatively non-invasive intervention compared to the currently available interventions. It does provide some criteria to determine the proper population for coverage.

Chang, JW, Park CK, Lipsman N, et al provided a 2-year follow up on the cohort of the above investigation.[1] The therapeutic effect does seem to be maintained and there were no apparent late adverse events. There was a 12% drop out rate, and the authors acknowledged the rate and accounted for the dropouts.

<u>Tremor-Dominant Parkinson's disease (TDPD)</u>
Tremor is a common motor feature of Parkinson disease (PD), and TDPD is a clinical subtype distinct from the akinesia/rigidity (AR) and postural instability/gait disorder subtypes. This subtype may be more resistant to dopamine-replacement therapy than other motor symptoms. DBS and traditional thalamic lesioning are accepted treatments of motor symptoms of PD. Several small observational studies also demonstrated efficacy of MRgFUS

thalamotomy in TDPD out to 1 year.[5-7, 9]

A small prospective, sham-controlled RCT looked at the safety and efficacy of unilateral MRgFUS thalamotomy at 3 and 12 months in patients with TDPD[3]. Twenty-seven patients (median age 67.8 years; interquartile range [IQR], 62.1-73.8) were randomized (2:1) to MRgFUS (20) vs. sham (7). Predefined primary outcomes were safety and difference in improvement between groups at 3 months in the on-medication treated hand tremor CRST subscore. Secondary outcomes included descriptive results of UPDRS scores and quality of life measures. Three-month on-medication median tremor scores improved 62% (17 to 4.5; IQR, 22%-79%) in the treatment group, and 22% (23 to 17; IQR, −11% to 29%) in the sham group (P = .04). Secondary outcomes showed non-statistical improvement trends in the treatment group. At 3 months, 6 sham patients crossed-over to MRgFUS treatment. Three months after crossover the median baseline CRST score improved from 21 to 5.5, like the 3 months outcomes in the group originally allocated to treatment. One-year follow-up of 14 treatment and 5 sham crossover patients demonstrated CRST score maintenance. Early in the study, heating of the internal capsule resulted in 2 cases (8%) of mild hemiparesis, which improved and prompted monitoring of an additional axis during magnetic resonance thermometry. Other persistent adverse events were orofacial paresthesia (20%), finger paresthesia (5%), and ataxia (5%). A sub-analysis reported no change in cognitive, mood, or behavioral perspective at 3 and 12 months.

On 12/16/2018, the Exablate MRgFUS device FDA indication was expanded to include unilateral thalamotomy (ventralis intermedius) treatment of TDPD with medication-refractory tremor in patients at least age 30.[4].

Analysis of Evidence (Rationale for Determination)

Level of Evidence for 0042T
The 2019 update to the 2018 American Heart Association (AHA)/American Stroke Association (ASA) guidelines [29] for the early management of patients with AIS state "In selected patients with AIS within 6 to 24 hours of last known normal who have large vessel occlusion (LVO) in the anterior circulation, obtaining CTP, DW-MRI, or MRI perfusion is recommended to aid in patient selection for mechanical thrombectomy, but only when imaging and other eligibility criteria from RCTs showing benefit are being strictly applied in selecting patients for mechanical thrombectomy". (Class of recommendation I-strong; level (quality) of evidence A) [30]. 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 hours) period (Class of recommendation I-strong; level (quality) of evidence B-Nonrandomized), or for any other indication (e.g., prediction of hemorrhagic transformation in acute ischemic injury). Other guidelines have similar recommendations [31-33].
The guidelines also caution that advanced, multimodal pretreatment imaging should not delay administration of IV tPA referencing "failed to demonstrate clinical efficacy in patients with various pretreatment imaging biomarkers compared with those without those markers" (Class of recommendation-III: Strong for Harm; level of evidence; quality of evidence B-NR).

National Institute for Health and Care Excellence recommends: "If thrombectomy might be indicated, perform imaging with CT contrast angiography following initial non-enhanced CT. Add CT perfusion imaging (or MR equivalent) if thrombectomy might be indicated beyond 6 hours of symptom onset." They also recommend thrombectomy with intravenous thrombolysis for occlusion of the proximal posterior circulation on CTA or MRA if CTP of DWI shows limited infarct core volume with the potential to salvage brain tissue [34]. However, there is minimal evidence regarding the appropriate threshold and utility of CTP in the posterior circulation, and accurate calculations are limited in posterior fossa by skull base and orbit artifact [14]. There is evidence DWI has an advantage over CTP for posterior fossa stokes, lacunar infarcts, and small watershed infarcts [14].

ECRI Clinical Evidence Assessment on Perfusion CTP reviewed the literature on CTP as an alternative imaging evaluation in addition to NCCT and determined the evidence was "inconclusive" due to mixed results. They report

"CTP's clinical utility compared with that of NCCT and magnetic resonance imaging (MRI) for assessing AIS has not been established because of too few data. No studies compared CTP clinical utility with other imaging methods. The RCT focused on treatment and did not randomly assign imaging methods, which created a risk of selection bias when comparing CTP to perfusion MRI. Most studies assessed in the SRs, as well as the diagnostic accuracy studies published after the SRs, were at high risk of bias due to retrospective design and single-center focus [21].

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. While there is a promise to CTP technology applied to other neuroimaging areas, there is still insufficient evidence. Other stroke or non-stroke indications, including routine assessment of AIS, determination of HT, and other indications, are not considered medically reasonable and necessary at this time.

Level of Evidence for 0525T-0532T
Evaluation of the evidence: The issue is whether to provide coverage of the service represented by CPT® 0525T-0532T. The 681 pages of material submitted is largely irrelevant to the issue. The articles that touch on the issue are marred by a weak methodology or at least a weak description of the methodology. (Pease see "Summary of the Evidence.") Coverage will be denied as not reasonable and medically necessary.

Level of Evidence for 0398T
Quality -Moderate
Strength - Moderate
Weight – Moderate

While more trials would be helpful, the evidence submitted in the reconsideration request does indicate that this may have a role in avoiding more invasive interventions. The evidence submitted also allows the establishment of indications for coverage and exclusions from coverage.

However, given the support for traditional thalamotomy, generally, as an alternative "if DBS is not available or practical", and the support for MRgFUS thalamotomy, specifically, as an alternative in patients "who are not a candidate for DBS" by the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the American Association of Stereotactic and Functional Neurosurgery (ASSFN)[8], WPS GHA considers MRgFUS reasonable and necessary in that context.

General Information

Associated Information

1. The patient's medical record must contain documentation that fully supports the medical necessity for services or procedures described by Category III CPT Codes as they are covered by Medicare. (See section entitled "Coverage Indications, Limitations, and/or Medical Necessity"). This documentation includes, but is not limited to, relevant medical history, physical examination, results of pertinent diagnostic tests or procedures, and any other records that describe or support the evaluation and treatment of the patient.
2. All claims containing any Category III code referenced in this LCD may be subject to review and denial if documentation is incomplete and does not support reasonable and necessary indications.

Utilization Guidelines

Coverage Determinations according to IOM 100-04 Medicare Program Integrity Manual prior to 01/08/2019.

Category III Codes discussed in this policy may be listed in separate WPS LCD and Billing and Coding Articles. For services addressed in a separate LCD and Billing and Coding Article, all criteria addressed in that LCD and Billing and Coding Article must be met.

CPT Codes 0501T-0504T: coverage in L35490 no longer applicable. Please refer to L38839 Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease
and A58473 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease for Coverage Indications, Limitations, and/or Medical Necessity. Effective 04/25/2021.

0075T, 0076T Refer to CMS publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1 – Coverage Determinations, Part 1, § 20.7 – Percutaneous Transluminal Angioplasty (PTA). Billing instructions are listed in the CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 32 – Billing Requirements for Special Services, Sections 160-160.3 – PTA for Implanting the Carotid Stent. As directed in The CPT 2018 Professional code book, use 0076T in conjunction with 0075T.

0184T The National Comprehensive Cancer Network (NCCN) guideline on treatment of rectal cancer states that, when criteria for transanal resection are met, transanal endoscopic microsurgery (TEMS) can be used when the tumor can be adequately identified in the rectum. It further states that TEMS for more proximal lesions (greater than 8 cm from anal verge) may be technically feasible.

0253T, 0474T An anterior segment aqueous drainage device, utilizing the internal approach, for use in combination with cataract surgery to reduce pressure inside the eye (intraocular pressure) in adult patients with mild or moderate open-angle glaucoma on medication.

0308T Effective July 1, 2012 CPT/ HCPCS code 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens) is payable. Further, claims submitted by Part A providers and ambulatory surgical centers for device pass-through category C1840 must be billed with HCPCS code 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens) to receive pass-through payment.

0394T, 0395T High dose electronic brachytherapy for skin surface application and for interstitial or intracavitary treatment, respectively. Was code 0182T prior to 01/01/2016. It is reimbursable with documentation of medical necessity.

0449T, 0450T Insertion of an aqueous drainage device is indicated for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open-angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

Sources of Information

This bibliography presents those sources that were obtained during the development of this policy:
Current Procedural Terminology (CPT®), Professional Edition (2019) American Medical Association.
Other MAC contractors policies

Bibliography

0042T

1. Lopez, A.D., et al., Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data. 2006. 367(9524): p. 1747-1757.
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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
03/28/2024	R32	Posted 03/28/2024-.Under **CMS National Coverage Policy** corrected citations under **Social Security Acts and CMS IOM Citations**. Punctuation and minor grammatical errors corrected throughout to AMA format. Under **Utilization Guidelines** removed all references to CPT code 0275T as this information is in NCD 150.13. Review completed 02/21/2024.	• Other ((Correction))
04/27/2023	R31	Posted 04/27/2023-Removed all reference to CPT code 0254T from LCD as this code was deleted 01/01/2020. References to CPT codes 0501T-0504T removed from Summary of Evidence, Analysis of Evidence, and Bibliography. Moved direction for CPT Codes 0501T-0504T: coverage to be found in L38839 Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease and A58473 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease for Coverage Indications, Limitations, and/or Medical Necessity under **Utilization Guidelines**.	• Other ((Correction))

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
06/12/2022	R30	Posted 06/30/2022-Under **Summary of Evidence 0501T-0504T** removed broken hyperlink and changed article citation to reflect AMA formatting.	• Other
06/12/2022	R29	Posted 04/28/2022. Under 0398T added coverage indications, exclusions from coverage and studies to support Tremor Dominant Parkinson's Disease. Added additional information for MRgFUS thalamotomy under Analysis of Evidence. Additional references were added under Bibliography section 0398T. Under **CMS National Coverage Policy** change requests and references were deleted and under Social Security Acts added "Title XVIII of the Social Security Act" was added to the beginning of the sentence on the last two bullet points.	• Other
01/01/2022	R28	02/01/2022 - Posted 02/10/2022 Under **Summary of Evidence 0501T-0504T** in paragraph 5 corrected hyperlink.	• Typographical Error
01/01/2022	R27	12/30/2021 Annual CPT/HCPCS Under **Utilization Guidelines** deleted codes 0191T, 0376T and 0548T thru 0551T and all information related to these codes. Under Summary of Evidence, Analysis of Evidence and Bibliography removed all information related to deleted code 0355T.	• Other (Annual CPT/HCPCS Code updates)
04/25/2021	R26	03/11/2021 Updated CPT Codes 0501T-0504T: coverage in L35490 no longer applicable. Please refer to L38839 Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease and A58473 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease for Coverage Indications, Limitations, and/or Medical Necessity. Effective 04/25/2021.	• Provider Education/Guidance
03/28/2021	R25	02/11/2021 Updated CPT Code 0355T: Denial of coverage is no longer applicable. Please refer to L38837 Colon Capsule Endoscopy (CCE) and A58471 Billing and Coding: Colon Capsule Endoscopy (CCE) for Coverage Indications, Limitations, and/or Medical Necessity. Effective 03/28/2021. 2021 CPT/HCPCS Annual code update: 0295T, 0296T, 0297T, and 0298T deleted. Effective 01/01/2021 and removed reference to LCD L34636 Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring) and A57476 Billing and Coding: Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring).	• Provider Education/Guidance • Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/29/2020	R24	10/29/2020: Reformatted CMS National Coverage Policy. Coverage Indications, Limitations and/or Medical Necessity updated: removed sentence #1 and #2 referencing Category III codes and removed last paragraph related to reconsideration process. Relocated medical necessity from utilization guidelines to Summary of Evidence for CPT codes 0042T, 0398T, and 0501T-0504T. Utilization Guideline statement updated and reformatted. Utilization Guidelines: updated 0548T-0051T: relocated billing and coding guidance of CPT code 0551T to A56902 and Change Request 11293 reference added.	• Provider Education/Guidance
07/01/2020	R23	06/25/2020: CMS National Coverage Policy added: CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.2.4- Proposed LCD. Summary of Evidence added: Coverage Determinations according to IOM 100-04 Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations and Change Request 10901, effective 01/08/2019, are listed below; CPT code 0042T with Summary of Evidence and Analysis of Evidence; CPT code range 0525T-0532T with Summary of Evidence and Analysis of Evidence. Level of Evidence for 0254T added Effective 01/01/2020 Category I code available. Please refer to the current CPT codebook. Utilization Guidelines added: Coverage Determinations according to IOM 100-04 Medicare Program Integrity Manual, prior to Change Request 10901, are listed below; Category III Codes discussed in this policy may be listed in separate WPS Medicare LCD and Billing and Coding Articles; For services addressed in a separate LCD and Billing and Coding Article, all criteria addressed in that LCD and Billing and Coding Article must be met. Reformatted: 0295T-0298T to include L34636 "Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring)" and A57476 Billing and Coding: Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring). Bibliography included for CPT code 0042T and CPT code range 0525T-0532T.	• Provider Education/Guidance
02/09/2020	R22	12/26/2019 Content updated related to reconsideration request for CPT codes 0254T and 0355T. Summary of Evidence, Analysis of Evidence and Bibliography related to reconsideration request included. Coverage is denied at this time for 0254T and 0355T. CPT/HCPCS annual update: deleted CPT 0254T. (Effective 01/01/2020) Providers are responsible for determining the correct diagnostic and procedural coding for the services they furnish to Medicare beneficiaries.	• Reconsideration Request • Other ((Reconsideration Request for CPT codes 0254T, 0355T))

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
01/01/2020	R21	12/19/2019 CPT/HCPCS annual code update: deleted CPT 0249T (true code available) from Utilization Guidelines in LCD and associated A56902 Billing and Coding: Category III Codes. Providers are responsible for determining the correct diagnostic and procedural coding for the services they furnish to Medicare beneficiaries.	• Revisions Due To CPT/HCPCS Code Changes
11/01/2019	R20	Content has been moved to the new template.	• Revisions Due To Code Removal
08/29/2019	R19	08/29/2019 Change Request 10901 Local Coverage Determinations (LCDs): it will no longer be appropriate to include Current Procedure Terminology (CPT)/Health Care Procedure Coding System (HCPCS) codes or International Classification of Diseases Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. All CPT/HCPCS and ICD-10 codes have been removed from this LCD and placed in Billing and Coding: Category III Codes linked to this LCD. Consistent with Change Request 10901 language from IOMs and/or regulations has been removed and the applicable manual/regulation has been referenced. There will not be a lapse in coverage and there has been no change to the coverage content of this LCD. Review completed 08/05/2019.	• Other (Changes in response to CMS Change Request 10901, review completed)
07/01/2019	R18	08/01/2019 Information from the Utilization Guidelines has been reformatted/relocated. CPT/HCPCS codes: Created Group 5 Paragraph and Group 5 Table to include CPT codes 0548T, 0549T, 0550T and 0551T. Removed duplicative language about CPT code C9746. Corrected minor typographical error. No change to content or coverage effective date.	• Provider Education/Guidance
07/01/2019	R17	06/27/2019 Added the statement to the Utilization Guidelines for 0548T - 0551T: Implantation of a transperineal periurethral balloon continence device is indicated for the treatment of adult men who have stress urinary incontinence arising from intrinsic sphincter deficiency of at least twelve months duration following radical prostatectomy or transurethral resection of the prostate (TURP) and who have failed to respond adequately to conservative therapy. Documentation must support that the patient has had a prostatectomy or transurethral resection of the prostate more than 12 months prior to placement of the device(s). CPT codes 0551T is only separately payable outside of the global period for 0548T and 0549T.Coverage will only be allowed when the service is	• Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		delivered in clinical situations meeting medical necessity. HCPCS code C9746 (Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed), which was effective July 1, 2017, was deleted June 30, 2019. C9746 has been replaced with CPT code 0548T and 0549T effective July 1, 2019. CPT Codes 0548T, 0459T, 0450T and 0551T and descriptions added. Refer to Change Request (CR) 11293: Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2019 Update and Change Request (CR) 11328: July 2019 Update of the Ambulatory Surgical Center (ASC) Payment System. Created Group 6 ICD-10 code table to include the following ICD-10 codes for CPT codes 0458T-0451T: N39.3, N39.42, N39.43, N39.44, N39.45, N39.46, N39.490, N39.491, N39.492 and N39.498. Please refer to Utilization Guidelines for additional information. Coverage effective 7/1/2019.	
01/01/2019	R16	01/01/2019 Annual review completed 11/30/2018. CPT/HCPCS Code Updates: deleted Group 3 Paragraph and corresponding Group 3 table of CPT/HCPCS codes 0387T, 0389T, 0390T and 0391T. (These leadless pacemaker codes now have true codes. See NCD 20.8.4.) Removed corresponding Group 3 Paragraph and Group 3 ICD-10 code Z00.6. Renumbered subsequent Paragraphs and Groups of codes. Removed the Utilization Guidelines language for 0387T, 0389T, 0390T, and 0391T For Part B only. Please see NCD for Leadless Pacemakers (20.8.4) for claims processing instructions (see CR 10117, Transmittal #3815, dated 07/28/2017). Removed the related National Coverage Documents: 20.8.4 – Leadless Pacemakers.	• Revisions Due To CPT/HCPCS Code Changes • Other (Annual Review)
09/01/2018	R15	09/01/2018 Removed language in the Utilization Guidelines for 0075T-0076T to refer to NCD 20.7 Percutaneous Transluminal Angioplasty. Updated IOM references.	• Other
07/01/2018	R14	07/01/2018 Added code 0398T to Group 5 table of CPT codes; added G25.0 to the corresponding Group 6 table of ICD-10 codes. Added information to the Summary of Evidence and Analysis of Evidence sections; added a statement to the Utilization Guidelines including Criteria for Medical Necessity and Exclusions from Coverage; and added resources to the Bibliography section.	• Revisions Due To CPT/HCPCS Code Changes • Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
06/01/2018	R13	06/01/2018 Added codes 0501T, 0502T, 0503T and 0504T FFRct to Group 4 table of codes. Added the statement to the Utilization Guidelines: 0501T - 0504T Fractional Flow Reserve computed tomography (FFRct) is a non-invasive method of using fluid dynamics physiologic stimulation software analysis to assess the severity of coronary artery disease. It is reimbursable with documentation of medical necessity. Added the corresponding Group 5 diagnosis codes: C38.0, C45.2, C79.89, C79.9, D15.1, I20.0, I20.1, I20.8, I24.0, I25.10, I25.110, I25.111, I25.118, I25.119, I25.2, I25.3, I25.41, I25.42, I25.5, I25.6, I25.700, I25.701, I25.708, I25.709, I25.710, I25.711, I25.718 I25.719, I25.720, I25.721, I25.728, I25.729, I25.730, I25.731, I25.738, I25.739, I25.750, I25.751, I25.758, I25.759, I25.760, I25.761, I25.768, I25.769, I25.790, I25.791, I25.798, I25.799, I25.810, I25.811, I25.812, I25.89, I25.9, I27.0, I31.0, I31.1, I31.2, I31.3, I31.4, I31.8, I31.9, I34.0, I34.1, I34.2, I34.8, I34.9, I35.0, I35.1, I35.2, I35.8, I35.9, I42.0, I42.5, I42.8, I42.9, I48.0, I48.1, I48.2, I48.3, I48.4, I48.91, I48.92, I49.01, I49.02, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84, I50.89, I50.9, I71.01, I71.1, I71.2, Q20.1, Q20.2, Q20.3, Q20.4, Q20.5, Q20.6, Q20.8, Q20.9, Q21.0, Q21.1, Q21.2, Q21.3, Q21.4, Q21.8, Q21.9, Q22.0, Q22.1, Q22.2, Q22.3, Q22.4, Q22.5, Q22.6, Q22.8, Q22.9, Q23.0, Q23.1, Q23.2, Q23.3, Q23.4, Q23.8, Q23.9, Q24.0, Q24.1, Q24.2, Q24.3, Q24.4, Q24.5, Q24.8, Q24.9, Q25.0, Q25.1, Q25.21, Q25.29, Q25.3, Q25.40, Q25.41, Q25.42, Q25.43, Q25.44, Q25.45, Q25.46, Q25.47, Q25.48, Q25.49, Q25.5, Q25.6, Q25.71, Q25.72, Q25.79, Q25.8, Q25.9, Q26.0, Q26.1, Q26.2, Q26.3, Q26.4, Q26.8, Q26.9, R06.02, R06.03, R07.2, R07.82, R07.89, R07.9, R94.30, R94.39. For 0501T-0504T: added resources to the Bibliography section and added information to the Summary of Evidence section and Analysis of Coverage section.	• Reconsideration Request
01/01/2018	R12	01/01/2018 Annual review done 12/01/2017, no change in coverage. Typographical corrections made. CPT/HCPCS code updates: description change to code 0474T.	• Revisions Due To CPT/HCPCS Code Changes • Other (Annual Review)
12/01/2017	R11		• Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		12/01/2017 Added the phrase "for Part B only" to the Group 3 Paragraph of CPT/HCPCS codes, to the Group 3 Paragraph of diagnosis codes, and to the Utilization Guidelines for codes 0387T, 0389T, 0390T, and 0391T.	
11/01/2017	R10	11/01/2017 Added codes 0449T and 0450T to Group 1 and created a Group 4 list of diagnosis codes for 0449T and 0450T: H40.10X3, H40.10X4, H40.1113, H40.1114, H40.1123, H40.1124, H40.1133, H40.1134, H40.1313, H40.1314, H40.1323, H40.1324, H40.1333, H40.1334, H40.1413, H40.1414, H40.1423, H40.1424, H40.1433, and H40.1434. Added the following information under Utilization Guidelines for the use of 0449T and 0450T: Insertion of an aqueous drainage device is indicated for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open-angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy. Added code 0253T to Group 1, to Group 1 Paragraph, and under Utilization Guidelines for an anterior segment aqueous drainage device.	• Revisions Due To ICD-10-CM Code Changes • Reconsideration Request
10/01/2017	R9	10/01/2017 ICD-10 code updates: to Group 2 deleted code M48.06 and added codes M48.061 and M48.062. Added code 0474T to Group 1 of covered CPT/HCPCS codes and to Group 1 Paragraph. Updated CMS National coverage information. Added language to Paragraph 2 to clarify claims processing for NCD 150.13 Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (PILD for LSS) for code 0275T. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Revisions Due To ICD-10-CM Code Changes • Reconsideration Request
09/01/2017	R8	09/01/2017 Added Group 3 Paragraph for coverage of Leadless Pacemakers, added Group 3 CPT codes 0387T, 0389T, 0390T and 0391T, and added Group 3 diagnosis code Z00.6 per NCD 20.8.4 effective 01/18/2017. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are	• Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		applicable as noted in this policy.	
01/01/2017	R7	01/01/2017 Annual review done 12/02/2016. Formatting changes made. Annual CPT/HCPCS code changes: description change to code 0275T; removed deleted codes 0171T, 0172T, and 0281T.	• Revisions Due To CPT/HCPCS Code Changes • Other (Annual Review)
11/01/2016	R6	11/01/2016 Added language to Paragraph 3 to clarify claims processing for NCD 150.13 Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (PILD for LSS) for code 0275T. Effective 10/01/2015.	• Other
10/01/2016	R5	10/01/2016 Per ICD-10 Code Updates: In Group 1: deleted codes H40.11X1 and H40.11X2 and added codes H40.1111, H40.1112, H40.1121, H40.1122, H40.1131, and H40.1132, effective 10/01/2016.	• Revisions Due To ICD-10-CM Code Changes
05/01/2016	R4	05/01/2016 Added 0249T to Group 1 codes effective 05/01/2016. Added 0281T to Group 4 codes effective 02/08/2016.	• Reconsideration Request • Other
01/01/2016	R3	01/01/2016 Annual review done 12/02/2015. Annual CPT/HCPCS code changes: deleted codes 0099T and 0182T; added codes 0394T and 0395T which replaced 0182T. Removed CAC information.	• Revisions Due To CPT/HCPCS Code Changes
11/01/2015	R2	11/01/2015 Added codes H40.11X1 and H40.11X2 to Group 1 Chart, to be effective 10/01/2015. Formatting changes made.	• Other (Diagnosis Code Update) • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R1	02/01/2015: CPT Code 0376T added to the policy as an add-on code to be used in conjunction with CPT Code 0191T.	• Revisions Due To CPT/HCPCS Code Changes • Other

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

DA56902 - (MCD Archive Site)
A56902 - Billing and Coding: Category III Codes
A58471 - Billing and Coding: Colon Capsule Endoscopy (CCE)
A57944 - Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea
A58213 - Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM)
A58473 - Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease
A58209 - Billing and Coding: Transurethral Waterjet Ablation of the Prostate
A59090 - Response to Comments: Category III Codes-(DL35490)

LCDs

DL35490 - (MCD Archive Site)
L38837 - Colon Capsule Endoscopy (CCE)
L35121 - Coronary Computed Tomography Angiography (CCTA)
L38528 - Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea
L38686 - Implantable Continuous Glucose Monitors (I-CGM)
L38839 - Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease
L38682 - Transurethral Waterjet Ablation of the Prostate
DL38682 - Transurethral Waterjet Ablation of the Prostate

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
03/20/2024	03/28/2024 - N/A	Currently in Effect (This Version)
04/21/2023	04/27/2023 - 03/27/2024	Superseded
06/23/2022	06/12/2022 - 04/26/2023	Superseded
04/20/2022	06/12/2022 - N/A	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A