Final Comments for Category III Codes (PHYS-082) L32569

WPS Medicare extends a thank you to all who reviewed the draft Category III Codes local coverage determination (LCD).

Comment:
WPS Medicare received multiple comments from the manufacture, providers, cardiologists and the Society for Cardiovascular Angiography and Interventions (SCAI) concerning the statement in the Category III draft LCD for the transcatheter aortic valve replacement procedure (TAVR). The statement that elicited concern and suggestions for improvement was written and included in the draft policy prior to release by CMS of the national coverage (NCD) decision memo. Once the NCD decision memo was issued it was determined by WPS Medicare that the draft LCD would require a revision for the provisions of CPT codes 0256T-0259T.

Response:
The WPP Medicare Category III Codes LCD has been amended to state;

> Claims for transcatheter aortic valve replacement (TAVR) will be individually reviewed. All claims meeting the criteria for coverage established by the National Coverage Determination (NCD) (Manual 100-3, Section 20.32) will be approved. Additionally, claims that are payable according to the NCD and are under an IDE trial must match the identified IDE number in the PRO field.

Comment:
A spokesperson for a large clinic asked the following question related to the TAVR procedure;

> Related to coverage of the TAVR procedure for a patient who meets the coverage requirements outlined in the decision memo, but who has femoral artery disease and needs a conduit at the level of the common iliac artery. Is there coverage if we must use a conduit to achieve femoral access?

Response
Medicare payment is based on the beneficiary meeting the appropriate criteria and medical necessity. Assuming coverage requirements have been met, determination to perform the TAVR procedure is left to the cardiology physician team caring for the patient.

Comment:
WPS Medicare received multiple letters supporting our decision to include 0275T, minimally invasive lumbar decompression (MILD) in the Category III Codes LCD.

Response:
WPS Medicare has determined that the MILD procedure (0275T) is eligible for coverage when medically necessary and therefore, CPT code 0275T is included in the Category III LCD.

Comment:
A reviewer of the MILD procedure asked the following question;

Procedure 0275T has been moved out of the main OR and now being performed in outpatient pain clinics (same site of service 22) as would be used for main outpatient or outpatient pain clinics do not have the same cleaning guidelines, room safety, nurse training nor are the patients getting the same type of sedation they would be receiving safely under the operating room rules. If this procedure has not been approved for ASC's or physician offices, then why would it be appropriate to do them in an outpatient clinic?

Response:

WPS Medicare expects all surgical procedures are only done in strict accordance with safety standards. The MILD procedure, specifically addressed in the comment above, is required by CMS, WPS Medicare, and expected the beneficiary to be performed as defined by CPT code 0275T, Further, regardless of place of service, the standard of care for this procedure dictates that it must be performed as follows; (1) using necessary sedation, (2) following sterile and aseptic techniques and (3) provided by trained staff

Comment:

A provider and a representative for the manufacture requested the addition of the following CPT codes;

1. 0291T (Intravascular optical coherence tomography (coronary native vessel or graft) during diagnostic evaluation and/or therapeutic intervention, including imaging supervision, interpretation, and report; initial vessel (List separately in addition to primary procedure) and
2. 0292T each additional vessel (List separately in addition to primary procedure)

WPS Medicare was told "OCT is an FDA approved alternative to intravascular ultrasound (IVUS) which outperforms it in diagnostic and therapeutic applications."

Response:

After a thorough review of your request and submitted evidence WPS Medicare has determined that the procedures defined by CPT codes 0291T and 0292T will remain deemed investigational and thus, non covered. At this time 0291T and 0292T lack general acceptance by the medical community. When available, additional scientific data published in peer-reviewed journals should be submitted via the reconsideration process to WPS Medicare.

Comment:

The Society for Cardiovascular Angiography and Interventions (SCAI) asked that the FDA determination of a 510(k) device statement found in the Indications and Limitations section of the LCD be modified and commented that some of the language conflicts with the NCD for Routine Costs in Clinical Trials (100-03, 310.1).

Response:

WPS Medicare does not agree that the language describing FDA determination of a 510K device published in the draft LCD is in conflict with the NCD for Routine Costs in Clinical Trials. However, as suggested by SCAI, for the purpose of improved clarity, the FDA determination of a 510(k) device statement in the Category III Codes LCD now reads;

> 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 (310.1O or in approved FDA Investigational Device Exemption (IDE) trial..

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.

Comment:
A request for inclusion of CPT Code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork) from the manufacture was received and reviewed.
Response:
After a thorough review of your request and submitted evidence WPS Medicare has determined that the procedure defined by CPT codes 0191T will remain deemed investigational and thus, non covered. When available, additional scientific data published in peer-reviewed journals should be submitted via the reconsideration process to WPS Medicare.

Comment:
A provider asked for inclusion of CPT code 0308T in the Category III Codes LCD.
Response:
CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens) is now included in the Category III LCD

Comment:
A request to include reference to PATH-033 for CPT codes 0279T and 0280T was considered.
Response:
Reference to local coverage determination, Circulating Tumor Cell Marker Assays, PATH-033 for CPT codes 0279T and 0280T has been added to this policy.

Comment:
Typographical errors, spelling, capitalization, and code description inconsistencies were identified. .
Response:
Spelling, code descriptions and grammatical errors have been corrected.

Comment:
CPT Code 0192T does not include ICD-9 codes 365.52 and 365.61. Should they be included in PHYS-082?
Response:

ICD-9-CM codes 365.52 and 365.61.have been added as payable diagnoses for CPT procedure 0192T (insertion of anterior segment aqueous drainage device, without intraocular reservoir; external approach).

Comment:
CPT Codes 0256T-0259T has guideline information in the policy. However, the codes are not listed in the table of CPT/HCPCS codes in PHYS-082. Should they be included?
Response:
CPT Codes 0256T-0259T (TAVR) are now listed in the table of CPT/HCPCS codes in PHYS-082.