

Frequently Asked Questions about Lung Cancer Screening and Medicare Coverage

Eligibility, Coding and Reimbursement

Can we start performing screening on Medicare beneficiaries immediately?

Yes, but you should hold claims until implementation guidance is available. Be sure that you are collecting the minimum data elements available in the CMS NCD document and are meeting the requirements of shared decision making and radiology eligibility criteria. You will be able to submit these claims later on.

The current NCCN guidelines, age also includes those individuals 50 years old or older with a 20 year pack year-and 1 additional risk factor; are these people no longer eligible?

According to the CMS decision, the NLST was the “only trial ...to show the benefits of lung cancer screening with LDCT.” They did not find evidence that other age criteria or smoking history was adequate to justify coverage however they indicate that they will consider modifying coverage in the future based on new evidence from research in other groups. LCA will be working to gather data to support consideration for appropriate expansion, in particular for the NCCN category 2a group.

How did CMS decide on the age range stopping at 77?

According to the NCD document, this was based on the results from the NLST. The enrollment age range was 55-74 with subsequent scans and benefits/harms data were recorded on participants up to and including 77 years of age. CMS did not feel there was adequate evidence to support screening in adults 78-80 years of age.

Can the 78-80 year olds who have Medicare pay for their scans if they choose to?

This is at the discretion of screening programs. Programs will not be reimbursed by CMS for screening this population, because it falls outside of their recommendation but there will not be any penalty for doing so.

Does CMS have a billable CPT code and charge for low dose lung cancer screening? If not, when do you anticipate this to be released so that we can begin screening?

A code has not yet been assigned but conversations are underway with the CMS payment staff but will take time to conclude. We will communicate this information as soon as it is finalized.

What is the Medicare reimbursement rate for screening?

Conversations with CMS payment staff have commenced. We will circulate this information when we have it. ACR has made some recommendations which can be found [here](#).

Once CMS releases implementation guidance, will reimbursement be backdated?

Once implementation guidance has been released, you can submit claims from February 5, 2015, which was the date that the final NCD was announced.

While we are waiting for final implementation guidance, can we continue self-pay for Medicare beneficiaries?

Self-pay is no longer necessary because of the final NCD which is covering Medicare beneficiaries in the high risk population. You should not continue self-pay for this covered population.

Will there be another document released at a later time when some of these other decisions are made i.e. coding, reimbursement, etc.? If so, what department would be releasing that document?

Yes. The CMS payment group will release the implementation guidance.

Registries

When will CMS announce the registries that have been approved?

The CMS coverage and analysis team has made it clear that approving registries is a top priority of theirs and we anticipate that they will post these approved registries very soon.

Is each center supposed to be a registry? I didn't understand the response about the registry fee being part of the screening payment.

Each center does not need to create its own registry to secure CMS reimbursement. Rather, each will need to provide data to a CMS approved registry. The reimbursement rate for lung cancer screening will take into consideration various parts of the process, including data submission efforts. We recognize that there are additional criteria required and mandated by the final coverage decision and we hope that the CMS reimbursement rate will reflect this reality.

Does the NPI number for the prescribing MD/NP/PA need to be stated on the order for the screening test; or is it just a matter of the practitioner having a NPI number?

The NPI number should be on the order but just needs to be in the records – this information is not submitted to CMS for billing.

Can a participating registry entity receive data from other registry entities for research purposes?

Does the registry require IRB approval at our sites?

The National Coverage Determination only addresses coverage. There are other entities at CMS that manage research studies and there would be different regulations regarding research

collection, including those related to IRB, HIPAA and other research ethics issues. Any use of a CMS registry for research purposes would require additional processes associated with the protection of research subjects.

Is the required patient identifier the MRN or something else?

The patient identifier required in the minimum required data elements list will be defined by the registry developer but would ultimately be an identifier that can be linked to Medicare claim numbers. This is often the individual's Medicare number but in this case, the registry will set the number.

Counseling and Decision Making

Who can do this counselling? Is CMS saying that only those practitioners at the prescriptive authority level (those most likely working in a primary care practice vs those of us working in a screening center/cancer center/radiology dept.) should be having this discussion with patients? / I am a nurse with an MSN, would I be qualified to do the counseling?

In the NCD document, CMS states: "We leave it to the discretion of the physician or qualified non-physician practitioner to determine whether other medical professionals should also participate in the visit based on a particular beneficiary's needs." In the conversation with Dr. Chin, he also indicated that the counseling and shared decision-making can be carried out by other healthcare personnel, such as RNs, under the supervision of a physician, PA, or Clinical Nurse Specialist (CNS) but ultimately those are the only people able to write the order and bill for the service.

Can Medical Assistants also provide counseling and SDM if under the supervision of the physician, CNS/APRN or PA?

A medical assistant, health educator, social worker or RN may provide counseling and SDM assuming that a supervising physician, PA or APRN/CNS ultimately provides the order for the scan. This is referred to as an "incident to" service and is further explained [here](#).

Should we include a statement on our standard prescription/order sheet indicating that counselling has been done and /or that the decision tool has been given/completed by the patient? Could the tool be a series of statements read and agreed to by the patient and signed by both?

Having a statement to indicate that counseling has been done is a good way to document this process. However, shared decision making is more than just statements read and agreed to by the patient. That is more like an informed consent, which is a legal document. We are currently working to identify shared decision-making tools that would be adequate to meet the basic recommendations of an SDM process.

We get calls from patients when their PCP has told them to call. If they don't have order, should the patient be seen by one of our MD to have the shared decision making process and then proceed with the scan?

*CMS requires a physician order for the screening to happen, and that order must include the proper counseling and SDM process. If the patient calls without an order, they would need to be seen by a physician, PA, or CNS before **being screening** to complete these requirements.*

Will a physical visit be required or can it be a virtual/telephone visit? What if it's a phone encounter with a nurse and no billing occurs but it IS documented and approved by the physician who writes the order?

The counseling and shared decision-making visit has to be an in-person visit. It cannot be by phone, online, or in a group. It must be a face-to-face office visit.

What documentation is necessary for SDM to ensure reimbursement? Will there be an audit of this information/how will it be monitored?

The counseling and SDM visit should be simply documented in the patient's medical record. This is not information that needs to be submitted to CMS as part of the billing process. While an audit is possible, it is not common.

Could you clarify whether we are required to use a specific tool for SDM or not and if so, what tools are acceptable? Can we create our own tool as long as it includes all required topics?

You are required to use a tested and validated decision aid as part of the shared decision making conversation. LCA is currently looking into these aids and will list them as soon as we can on our website [here](#).

What is responsibility for the imaging center/hospital radiology department which is separate from a MD office to verify/ensure that a shared decision making visit containing all required elements has occurred with the MD? In other words, will the radiology department/radiologist be penalized and denied payment if the shared decision making visit is not well documented by the PCP but the PCP submitted a valid order for a LDCT?

The practice conducting the imaging will not be penalized for sub-optimal SDM. In the unlikely event that there is a denial, the claim would just need to be resubmitted showing proper documentation. Regardless, the implementation guidance being developed will provide more detail on how to implement this process.

What modality or modalities are acceptable to facilitate the "any appropriate visit" needed to initiate subsequent written orders for LDCT LCS?

While the initial screening order must be accompanied by a separate visit for counseling and shared decision-making, for subsequent screening, any preventive service, E/M, wellness,

routine visits with the referring provider can be considered an “appropriate visit” for providing the order.

Miscellaneous

Regarding the following radiology requirement: “Utilizes a standardized lung nodule identification, classification and reporting system,” we know that ACR LungRADS is a standard reporting system. What other reporting systems are considered adequate?
Currently, CMS has indicated that LungRADS is the only standardized nodule identification, classification and reporting system that they have seen but they suspect that others may surface for consideration.

It does not look like we need our CT scanner certification anymore, like the preliminary decision memo had stated. Is this true?/ I am hearing that sites need to be accredited in CT in order to bill for these exams. I have not found that I writing. Can you verify this or tell me if it is not true?

The NCD decision memo indicates in the discussion section that advanced diagnostic imaging accreditation is no longer required.

When will CMS be updating the guide for Medicare patients How much detail about this CMS coverage (e.g., eligibility criteria, risks/benefits, ongoing screening, etc.) will CMS include in its updated guide (current version attached below) for Medicare Patients?

CMS will likely update the Medicare website soon with information but doesn’t update the written guidance as frequently (generally on a yearly basis). They will let us know when the details are updated.