Program Memorandum Intermediaries/Carriers

Department of Health & Human Services (DHHS)
Centers For Medicare & Medicaid Services (CMS)

Transmittal AB-02-134 **Date: OCTOBER 4, 2002**

CHANGE REQUEST 2383

SUBJECT: Questions and Answers Related to Implementation of National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services

Program Memorandum (PM) AB-02-087 and AB-02-110 provided instructions related to implementation of the 23 NCDs for clinical diagnostic laboratory services that were established under the negotiated rulemaking (66 FR 58788) and published in the *Federal Register* on November 23, 2001. We have contracted for the development of an edit module that will be plugged into the shared systems so that claims for outpatient clinical diagnostic laboratory services that are covered under the NCDs will be handled in an identical manner regardless of where they are processed. We have had numerous questions since publication of these PMs. We are issuing this PM to clarify information related to implementation of the NCDs.

Q1. The NCDs become effective on November 25, 2002. How is this applied?

A1. The effective date of the NCDs is for services furnished on or after November 25, 2002. The NCDs will be applied on a date of service basis.

Q2. Since implementation of the system edits to apply the NCDs will be delayed until January 1, 2003, should laboratory hold claims with dates of service on or after November 25, 2002 until then?

A2. No, it is not necessary for laboratories to hold claims until January 1, 2003. Medicare claims processing contractors have been instructed to review their local medical review policies (LMRP) to ensure that they do not conflict with the NCDs by November 25, 2002. If there is no conflicting LMRP for the test in your area, the claim should not be edited and, in most cases, will be paid. Laboratories should identify claims that are not appropriate for payment under the new NCDs by using the GA, GZ and GY modifiers, as appropriate (see A3 below). Contractors may conduct post-payment review of laboratory claims that are subject to the NCDs to ensure appropriate payment. As a result, erroneously paid claims may be adjusted and erroneous payments maybe recovered.

Q3. PM AB-02-110 states that laboratories should use the GZ modifier for claims where the diagnosis is in list 2, ICD-9-CM codes denied. The GZ modifier is for services that are not medically necessary. Is this the correct modifier?

A3. Most of the items in list 2 are not covered for statutory reasons other than medical necessity. Labs should use the GY modifier for items that are not covered for reasons other than medical necessity. For items in list 3, ICD-9-CM codes that do not support medical necessity, use the GA modifier for cases where an advance beneficiary notice (i.e., a waiver of liability statement) is on file or the GZ modifier when there is not an advance beneficiary notice on file.

Q4. The NCD for urine culture includes in the list of CPT codes tests that can be performed to identify bacteria for urine and other purposes. Specifically, CPT codes 87184 and 87186 are for sensitivity studies and are not specific to urine. Concern was raised with editing these CPT codes generally with the diagnosis listed in the covered list.

A4. It is true that CPT codes for sensitivity testing are not specific to urine. Editing of these CPT codes with the list of covered diagnosis is likely to result in inappropriate denial of these services when they are performed on specimen other than urine. The edit module will not edit for these CPT codes. Rather, they will return a “not applicable” response from the edit module. Contractors are free to edit these codes locally either on a pre-payment or post-payment basis.

Q5. What happens to those codes not included in one of the three lists?

A5. Every single ICD-9-CM code falls into one of the three lists. Each of the 23 NCD policies has a section that states the codes covered for that policy, the codes denied for that policy, and the codes that (generally) do not support medical necessity. Two of the lists will list specific codes while the third list consists of a default category consisting of any ICD-9-CM codes not listed in the other two.

Q6. How will the edit module treat claims where the diagnosis is in list 3, ICD-9-CM codes that do not support medical necessity?

A6. Some contractors have the ability to use an electronic indicator on the claims to show that there is documentation submitted with the claim. Where the indicator is not present, a deny response will be issued, unless the claim is accompanied by an override code. Where the indicator is present on the claim, the edit module will send back a suspend response. Contractors may not deny these suspend claims unless they have reviewed the documentation and made a determination that the documentation does not support medical necessity of the service. Contractors may pay suspend response claims without review of the documentation.

In cases where the contractor does not currently have the capability to use an electronic documentation indicator, contractors should either instruct laboratories to submit claims hard copy or develop some other mechanism for the laboratories to notify the contractor that documentation should be associated with the claim. Contractors will then make a decision to either pay the claim without review of the documentation or review the documentation and make a decision based on the evidence supplied. If the decision is to pay the claim, the contractor should use the override code to indicate such so that the edit module will send a pass response. Claims sent to the edit module without the override indicator or the documentation indicator will receive a deny response. See the specifications for the edit module for additional information regarding the record layout for transmitting this information to the edit module and appropriate values.

Q7. How should contractors correct any claims that were denied in error due to failure to override the edit module?

A7. Contractors should reopen claims as authorized by the regulations.

Q8. What MSN messages should be used for denial of claims under the NCDs?

A8. The edit module will produce two different deny responses. For those services where the response is based on the diagnosis being included on list 2, ICD-9-CM codes that are not covered by Medicare, use MSN message 21.11, service not covered by Medicare. For those services where the denial response is based on the diagnosis being included on list 3, ICD-9-CM codes that do not support medical necessity, use MSN message 15.4, services not medically necessary.

Q9. How will the edit module handle multiple services with a date code that spans the effective date of the NCDs?

A9. If the through date of the claim is on or after the effective date, all services on the claim will be edited. In order to avoid claims being edited by the module inappropriately, a provider may split the bill into two bills—one for services prior to the effective date and one for services on or after the effective date. Carriers may also allow providers to split the services onto individual claim lines as well, if their systems allow the claims to be appropriately processed this way.

Q10. The laboratory final rule makes an exception to the date of service for specimens that have been stored. The date of service for stored specimens is the date the specimen is removed from archives. Sometimes, a laboratory may store a specimen for a day or two before testing. How long does a specimen need to be stored in order to qualify for this exception?

A10. The final rule did not define the period of time a specimen needs to be stored in order to qualify for this exception. In the absence of national instructions, contractors have the discretion to further clarify the criterion for this exception. The intent of the exception was to recognize long storage periods that occurred prior to testing. Contractors can address the exact length of time on an individual basis.

Q11. What are the allowable bill types for clinical diagnostic laboratory services?

A11. The allowable bill types are 12X, 13X, 14X, 22X, 23X, 72X, 74X, 75X, 76X, 83X, and 85X. Clinical diagnostic laboratory services may not be billed on 21X, 32X, 33X, 34X, 71X, 73X, 81X, or 82X bill types.

The *effective date* for this PM is services furnished on or after November 25, 2002.

The *implementation date* for this PM is January 1, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after September 30, 2003.

If you have any questions, contact Jackie Sheridan at (410) 786-4635.