Appendix 7-3

Lung Screening Study

Specifications for Completion of the Medical Record Abstract Form: Diagnostic Evaluation

This form is to be completed by the Medical Record Abstractor, a nosologist (trained medical coder), and a Tumor (or Cancer) Registrar who is also a Certified Tumor Registrar (CTR) or CTR – eligible. Items that are to be completed by a nosologist or a CTR or CTR-eligible individual are specified. The abstractor should complete all other items. Specifically, the nosologist will be required to complete Item B.11 (ICD-9-CM Classification of Physician Diagnosis) if it requires coding of a cancer, a neoplasm of uncertain behavior, or carcinoid-origin other than lung. The CTR or CTR-eligible individual will be required to complete Items C.18 (ICD-O-2 Cancer Classification), C.20 (Histopathologic Type for Primary Lung Cancer), C.21 (Histopathologic Grade for Primary Lung Cancer), C.22 (TNM Staging for Primary Lung Cancer), and C.23 (Record Stage).

Refer to Chapter 7 of the Manual of Operations and Procedures. Some guidelines for general abstracting are presented below:

- Sources of information are specified, where appropriate, for abstracting the variable items on the form. The sources of information are listed in priority order by best source. Note that information must be obtained from a physician, hospital, or tumor registry; it should not be obtained from the participant. Written documentation from the physician or the medical record, for example, is preferable to obtaining information verbally.

  - An exception to the above is Item A.7 (Did participant undergo diagnostic procedures?), in which the response may be based on participant self-report.

- Medical records documenting diagnostic evaluation and staging procedures should be collected for all positive screens. Records should be collected on all procedures occurring on or before the date of conclusive diagnosis (including staging) or on or before May 1, 2001, whichever comes first. Records may be collected through May 31, 2001. Medical records documenting complications of diagnostic evaluations or staging procedures performed on or before May 1, 2001 should also be collected. These records should be collected for complications that occur up to two months after the date of diagnosis or May 31, 2001, whichever comes first.

- Before beginning abstraction, the medical record documents should be placed in chronological order and the diagnostic/staging procedures should be abstracted chronologically. If, however, a diagnostic or staging procedure is identified and added after the form has been completed, it is not necessary to shift all of the data to maintain the chronological order; the new procedure may be added at the end of the appropriate item.

- This form includes items that require that data be entered verbatim, such as recording "other (specify)," and recording information in Item B.14, Comments. The abstractor should be sure to use clear and legible handwriting when completing these items.

- If the medical record contains unclear, discrepant, or conflicting information for any item, the SC Coordinator and/or Principal Investigator should first be consulted for a resolution and for making an appropriate coding decision, prior to contacting the CC.

- When recording information in the Comments section (Item B.14), it is necessary to appropriately identify to which item the comment refers. Appropriate identification will aid in the analysis of Comments data. Throughout the specifications, identifying phrases have been suggested for use when recording information in Comments.

Below are some guidelines for the collection of diagnostic evaluation information:

- The initial Lung Screening Study exam should not be recorded.

- Information regarding diagnostic procedures that occurred prior to the participant's screening date should not be recorded.

  By May 1, 2001, if the diagnostic evaluation has not resulted in a final diagnosis of malignancy, record the result of the diagnostic evaluation as "No malignancy." There are two exceptions to this:

  - Diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a lung or other malignancy. In this situation it is not appropriate to record a conclusive diagnosis, but rather to record "No information available," and a verbatim description of the situation in Item B.14, Comments.

  - Diagnostic evaluation shows a very small nodule (either new or present on the screening exam), and the decision is made to followup in 2 to 3 months. In this situation it is <u>not</u> appropriate to record "No malignancy," but rather to record "Further Followup Required."

  It is the SC's responsibility to encourage timely follow-up of positive screens. If, despite SC efforts, the participant does not initiate follow-up of a positive screen for several months, the SC must still adhere to the timeline set forth above for acquisition of medical records.

- All staging information related to the initial diagnosis of primary lung cancer should be collected (i.e., the staging procedures that resulted in the TNM or stage of disease classifications recorded in Part C of the DE form). Staging information on lung cancer recurrence should not be collected.

- If multiple primary lung cancers are diagnosed at the same time (i.e., as part of the same diagnostic evaluation process and prior to the first definitive treatment), it is necessary to complete a separate DE for each primary. Item 4 allows the SC Coordinator to indicate whether the DE is being used for abstracting information about one of multiple primary lung cancers.

Specifications for completing each item of the form are given below:

<u>Administrative Section</u>:

Participant ID: Affix a PID label to the box provided at the top of the form.

1. **Date Abstracted:** Record the date the medical record was abstracted. This is the date the form was completed. Zero fill month and day, and record two digits for year (i.e., 02/05/20<u>01</u>).

2. **Abstractor ID#:** Record the 4-digit staff ID number assigned to the individual who is abstracting the medical record and completing the DE. If more than one abstractor completes the DE, the SC Coordinator should determine which abstractor is responsible for the content of the form -- it is this abstractor's ID number that should be recorded here. If this abstract is for QA (see Item 3), this should be the QA abstractor's ID number.

   - The nosologist and CTR or CTR-eligible individual should not record their ID numbers in this item. There is space for the nosologist and CTR or CTR-eligible individual to record their own staff ID numbers for the specific items which they complete in Item B.13 and C.18.

3. **Purpose of Abstract:** This form may be used for either the initial abstracting of medical record information, or for repeat abstraction of the medical record for quality assurance. Check the box corresponding to the purpose of the abstract as follows:

   Initial abstract: Medical record information is being abstracted for the "first" time to followup a positive screen.

   Re-abstract for QA: Medical record information which has already been abstracted to followup a positive screen, is being re-abstracted for the purpose of quality assurance.

4. **Multiple Primary Lung Cancer #:** The purpose of this item is to indicate whether this form is being used to abstract information about an additional primary lung cancer that was diagnosed at the same time as the first primary lung cancer (i.e., as part of the same diagnostic evaluation and staging process and before the first definitive treatment). Indicate the sequence number for the primary cancer. The first primary cancer is sequence number 1 and should be abstracted on a separate DE form. If this primary cancer is the second primary diagnosed (in chronological date order), enter number "2". If it is the third, enter "3", etc.

   NOTE: In cases where no primary lung cancer or only one primary lung cancer was diagnosed, this item should be coded NA.

5. **Form Processing:** These are the steps that should be completed in order to process the examination form.

   Manual Review Completed: Check this box after the form has been reviewed by SC staff to make sure that the information is complete, legible and that the appropriate boxes are checked. (Refer to Chapter 9 for instructions on performing a manual review of forms.)

   Sent to CC: Check this box after the form has been copied and the original transmitted to the CC. A copy should be stored in the participant's study file. See Chapter 9 of the Manual of Operations and Procedures for information on transmittal of forms to the CC.

6. **Disposition:** This section is to be completed by the CC only. The CC will assign a final disposition to each form. There are two final dispositions:

   FCM (Final Complete): This disposition is assigned when all sections of the DE have been completed and edited by the SC.

   FIC (Final Incomplete): This disposition is assigned when information is missing from the DE, that cannot be corrected.

Part A: Diagnostic Evaluation and Staging:

This section refers to the diagnostic evaluation. Abstracting this data will require careful review of the participant's medical records at one or more hospitals, clinics, or physicians' offices.

When abstracting information onto this form, do not include information from any physician/hospital visits or procedures that took place prior to the participant's screening exam, even if these visits or procedures are related to a diagnosis that was made after the participant was enrolled in the trial.

7. **Did participant undergo diagnostic procedures?** The purpose of this item is to document whether or not diagnostic procedures were recommended by a physician and performed as part of the follow-up to a positive screening exam (chest X-ray or spiral CT). Check the box corresponding to the most appropriate response as follows:

   Yes: The record indicates that diagnostic procedures were recommended by a physician and were performed. This includes situations when diagnostic procedures were performed to follow-up a positive screening exam (chest X-ray or spiral CT), or when an internal referral is done. In the latter situation, the internal review should be recorded as the first Diagnostic/Staging procedure. Complete Table A.8.

   No, Physician Report: The record indicated or the physician reported to the SC that based on review of the Lung Screening Study exam results, and possibly any medical history prior to the screening exam, no additional follow-up was deemed necessary. Complete Item A.10 (Result of Diagnostic Evaluation for Primary Lung Cancer) and Part B (Diagnosis Information for Any Condition Other Than Primary Lung Cancer).

   No, Participant Self-Report: The participant reported that the physician reviewed the Lung Screening Study exam results, and possibly other medical history prior to the screening exam, and deemed no additional follow-up was necessary. Complete Item A.10 (Result of Diagnostic Evaluation for Lung Cancer).

   - *Before accepting a participant self-report the SC should first attempt to obtain written documentation from the participant's physician. If written documentation cannot be obtained from the physician, the SC should then attempt to obtain verbal confirmation from the physician's office that the physician did not recommend additional follow-up of the positive screening exam. In cases where only the participant's report of the physician's recommendation can be obtained, this box should be checked.*

8. **Diagnostic Evaluations:** The following are general guidelines for identifying diagnostic and staging procedures in the medical record:

   - Only procedures used to diagnose or stage a cancer that are clearly stated in the record (discharge summaries and operative reports) should be recorded. If the operative report and/or discharge summary is missing, procedures noted in doctor's notes or a history taken *after* the procedure may be used to record a diagnostic/staging procedure. *Please call the CC if there is any uncertainty about recording diagnostic/staging procedures.*

   - Following a positive screening exam (chest X-ray or spiral CT), the SC should collect information on diagnostic procedures occurring on or before the date of conclusive diagnosis (including staging) or on or before May 1, 2001, whichever comes first.

For each diagnostic/staging procedure performed, complete the following items:

Procedure #: Enter the information regarding each procedure on a separate row.

Date of Procedure: Record the month, day, and year that the diagnostic/staging procedure was performed. If it is not clear from the record the date that the diagnostic/staging procedure was performed, year and month can usually be assessed, even if the exact date cannot be determined. In this situation, record the exact month and year and the day as "99". Zero fill month and day, and record two digits for year.

Type of Procedure: Enter the number corresponding to the type of diagnostic/staging procedure performed. Refer to the Procedure Codes for the list of diagnostic and staging procedures for primary lung cancer. When the procedure on the Procedure Code list indicates "SPECIFY," describe the body site or the actual procedure, as appropriate, in the space next to the code. The following are guidelines for coding type of procedure:

- **Laboratory Tests**: Pulmonary function tests and Cytology (sputum, bronchial washing/brushing) reports are the only laboratory tests to be recorded

- **Clinical Evaluation**: A clinical evaluation (clinical assessment) by a health care provider should be recorded in this section. A clinical evaluation is defined as a visit to a health care provider for medical care and should include a history and physical exam related to the organ of interest. If a history includes information about the positive screening exam only, this is to be considered a clinical evaluation. It does not include a telephone conversation to a health care provider. A clinical evaluation that only serves to repeat or confirm previous findings should not be recorded. The following examples illustrate how the form should be completed to document a clinical evaluation:

  - If a visit to a health care provider includes a history as well as a physical examination of the lungs, this is considered a clinical evaluation. Document this clinical evaluation using procedure code 14 = Clinical evaluation.

  - If a visit to a health care provider includes *only* a history and not a physical examination of the lungs, this is also considered a clinical evaluation. Record this procedure using 14 = Clinical evaluation.

- **Telephone conversation:** If a telephone conversation occurs with the health care provider and no other follow-up occurs, document this conversation using procedures code 36=Other (Specify). A telephone conversation is not considered a clinical evaluation; therefore, do not code 14=clinical evaluation.

- **Chest Radiographs:**

  - Chest radiograph = 13 should be used to code a diagnostic chest X-ray. Use this code when a diagnostic chest X-ray is in the record, regardless of whether a particular view is specified such as PA, lateral, Bucky, kyphotic, or lordotic.

  - Comparison with previous spiral CTs or chest X-rays = 15 should be coded in the instance of an internal referral or other review of multiple scans.

- **Biopsy Procedures:**

  - Needle Aspiration Biopsy: There are several codes for a fine needle aspiration of the lung as described below:

  - Use code 05 if a Transbronchial needle aspiration (TBNA) is specified *or* if a "Transaxillary oblique approach" is used.

  - Use code 06 if a Transthoracic needle aspiration (TNA) is specified.

  - Use code 07 = Biopsy – Needle aspiration - Other, if there was a needle aspiration performed but type is not specified.

  - 08 = Biopsy - Other (Specify): Record the site of the biopsy next to the code, not the method of biopsy. Use this code to record both incisional and excisional biopsies of organs other than the lung.

- **Lymph Node Procedures**:

  - If lymph node sampling and lymph node dissection are both performed, this should be considered as one procedure and recorded only once as 29 = Lymphadenectomy/Lymph Node Sampling.

    Lymph node removal accompanying surgical resection should be coded as two separate procedures. Code both procedures separately under the appropriate codes.

- **Resection:** While a lobectomy and pneumonectomy are treatments for lung cancer, record 43 = Resection if a wedge resection, lobectomy, or pneumonectomy provides diagnostic/staging information.

- **CT Scans**: If CT pelvic and CT abdominal procedures appear in the record as a combined procedure, they should be recorded as a single procedure under 17 = CT of the abdomen and pelvis combined, with one date. If they are performed on the same date, and appear in the record as separate procedures, the abstractor should record them separately under 22 = CT scan – other (SPECIFY).

9. Medical Complications: The only medical complications to be collected include the medical complications that are currently listed on the DE under Complication Codes. General guidelines for identifying these selected medical complications in the medical record are given below:

- Only those selected medical complications that were a result of the diagnostic evaluation or staging procedures *and that required medical attention* should be recorded.

- Information on medical complications can usually be found in the discharge summary, or the doctor's or nurse's notes within the medical record.

- Medical complications that occur up to two months after the date of diagnosis or May 31, 2001, whichever comes first, should be collected.

  No: If the review of the medical record indicates that none of the selected medical complications occurred, check the box labeled "No", and go to A.10.

Yes: If the record states or indicates that one or more of the selected medical complications listed on page 2 of the DE form resulted from a diagnostic or staging procedure, enter the date and the code for the complication(s) in the table. Record all complications occurring on a given date on the same line.

The following are guidelines for coding some of the medical complications:

02 = Allergic reaction: The record indicated that the participant experienced an allergic reaction, including swelling, itching, or rash (with or without local redness and warmth) that required treatment as a result of a diagnostic or staging procedure.

03 = Anaphylaxis: The record indicates that the participant experienced anaphalaxis, a severe allergic reaction with a dramatic drop in blood pressure, severe wheezing, or dramatic swelling and requiring treatment with supplemental oxygen, possible intubation or intravenous fluids as a result of a diagnostic or staging procedure. Anaphylaxis is a life-threatening condition.

17 = Hospitalization: Use only if reason for hospitalization is not another selected complication.

20 = Infection (SPECIFY): The record indicates that the participant had an infection as a result of a diagnostic or staging procedure. Specify the site or source of the infection on the line provided.

23 = Pneumothorax: The record indicates that the participant had a pneumothorax, an accumulation of air or gas in the pleural cavity, as a result of a diagnostic or staging procedure. A pneumothorax may be considered a medical complication that required intervention when the medical record indicates one or more of the following situations: (1) chest tubes are inserted into the thorax *following* a diagnosis of pneumothorax, (2) the patient remained in the hospital additional days for observation because of a pneumothorax, and/or (3) special diagnostic procedures (non-standardized radiographic views or serial chest X-rays for several days) were required before the patient was discharged from the hospital.

Unknown: If you do not have all of the medical records and you cannot reliably determine complications, check the box labeled "Unknown" and go to Item A.10.

10. Result of Diagnostic Evaluation for Primary Lung Cancer: The purpose of this item is to record the overall results of the diagnostic evaluation for primary lung cancer. This information should be found in the impression/conclusion sections of the various diagnostic and staging reports.

- Following a positive screening exam (chest X-ray or spiral CT), the SC should collect information about diagnostic procedures occurring on or before the date of conclusive diagnosis (including staging) or on or before May 1, 2001, whichever comes first.

- If a cancer is not confirmed or staged until treatment is performed, information regarding that treatment should be abstracted onto the DE.

Record the result of the diagnostic evaluation for primary lung cancer as follows:

No malignancy: The record indicates that no malignancy was found as a result of the diagnostic and staging procedures.

A result of "No malignancy" should also be coded in the following situations:

- When no diagnostic procedures are performed following a positive screening exam – (i.e., when Item A.7: Did participant undergo diagnostic procedures? is coded "No, physician report," or "No, participant self-report").

- When diagnostic follow-up data have been abstracted for the period from a positive screen through May 1, 2001, and the diagnosis was not conclusively malignant.

- Check the box and go to Part B: Diagnosis Information for Any Condition Other Than Primary Lung Cancer.

Atypical adenomatous hyperplasia: The record indicates that the participant has been diagnosed with atypical adenomatous hyperplasia. Check the box, and complete Part B: Diagnosis Information for any Condition Other than Primary Lung Cancer.

Squamous dysplasia: The record indicates that the participant has been diagnosed with squamous dysplasia. Check the box, and complete Part B: Diagnosis Information for any Condition Other than Primary Lung Cancer.

Diffuse idiopathic pulmonary neuroendocrine hyperplasia: The record indicates that the participant has been diagnosed with diffuse idiopathic pulmonary neuroendocrine hyperplasia. Check the box, and complete Part B: Diagnosis Information for any Condition Other than Primary Lung Cancer.

Carcinoma in situ: The record indicates that the participant has been diagnosed with carcinoma in situ, confirmed by histologic examination. Carcinoma in situ is defined as malignant cell changes in the epithelial tissue that have not extended beyond the basement membrane of the mucosa. In situ may also be expressed as intraepithelial, non-infiltrating, non-invasive, pre-invasive, or no stromal invasion. Check the box, and complete Part B: Diagnosis Information for any Condition Other than Primary Lung Cancer.

Primary lung malignancy confirmed histologically: The record indicates that the participant has been diagnosed with primary lung cancer, confirmed by histologic examination (study of tissue). Histologic information may come from a biopsy, and can be found on the pathology report, sometimes called a histopathology report. Check the box and complete Part C: Primary Lung Cancer Diagnosis Information.

Primary lung malignancy confirmed cytologically: The diagnosis of primary lung cancer was confirmed by cytologic examination (study of cells). Cytologic information may come from a bronchial brushing or washing, or a fine-needle aspiration, and can be found on the cytology report, sometimes called a cytopathology report. Check the box and complete Part C: Primary Lung Cancer Diagnosis Information.

NOTE: If the lung malignancy was confirmed by both histologic and cytologic examination, information should be abstracted only from the histopathology report (even if the cytology report is earlier). The histopathology report is more definitive, and therefore, every attempt should be made to determine if one exists before utilizing cytologic confirmation. If the lung malignancy was confirmed by cytologic examination alone, then cancer diagnosis information should be taken from the cytology/cytopathology report.

Primary lung malignancy diagnosed by clinical examination only: The record indicates that the participant has been diagnosed with primary lung cancer by clinical examination and not confirmed by histologic examination (study of tissue) or cytologic examination (study of cells). It is an extremely rare event, however, for a malignancy to be confirmed only by clinical examination and not histologically or cytologically. Check the box and complete Part C, Primary Lung Cancer Diagnosis Information.

In these cases there will be a "holding period" through May 1, 2001, to be sure that no pathologic confirmation followed. The following guidelines should be used to determine if the diagnosed "clinically" code is appropriate:

- If the initial response is "clinically" and there is histologic or cytologic confirmation before May 1, 2001, the diagnosis code should be changed to "histologically" or "cytologically" and the diagnosis date should be updated.

- In all other instances, the "clinically" code should remain.

Other malignancy confirmed histologically or cytologically: The diagnosis of a malignancy other than primary lung cancer was confirmed by histologic examination (study of tissue) and or cytologic examination (study of cells). Histologic information can be found on the pathology report, sometimes called the histopathology report, and cytologic information can be found on the cytology report, sometimes called a cytopathology report. Check the box and go to Part B: Diagnosis Information for Any Condition Other Than Primary Lung Cancer.

- This answer category should also be coded if the diagnostic evaluation for primary lung cancer reveals a malignancy (including a lung malignancy) that is a *metastasis* from a primary cancer site other than the lung. In this situation, the *primary* cancer site should be recorded in Part B: Diagnosis Information for Any Condition Other Than Primary Lung Cancer.

Further followup required: The record indicates that very small nodule(s) were identified, and the decision was made to re-evaluate the nodule(s) in two to three months. This code should be used when the record clearly indicates that further followup is required. Check the box. Item B.14, Comments, should be used to record the reason for further followup.

No information available: There is equivocal or no information available in the record regarding the result of the diagnostic evaluation for primary lung cancer. Check the box and go to Part B.14: Comments, and record the reasons that a diagnosis could not be recorded.

- "No information available" should also be coded in the situation when diagnostic evaluation procedures are begun, but are later discontinued by the participant, such that it cannot be determined conclusively whether the participant had no malignancy or had a lung or other malignancy.

Part B: Diagnosis Information for Any Condition Other Than Primary Lung Cancer:

Only these specified diagnoses resulting from the diagnostic evaluation will be documented in this section: any cancer other than lung, any neoplasm of uncertain behavior that is from a site other than the lung, and the following selected conditions: atypical adenomatous hyperplasia, squamous dysplasia, diffuse idiopathic pulmonary neuroendocrine hyperplasia, carcinoma in situ (lung), emphysema, COPD, pneumonia, granuloma, hamartoma, candida, fungal infection of the lung NOS, tuberculosis, other mycobacterium of the lung, histoplasmosis, coccidioidomycosis, cryptococcosis, aspergillosis and/or solitary lung nodules. The diagnosis should be recorded from documents in the medical record that are prefaced with "Diagnosis/Impression/Conclusion/Assessment". This information will most likely be obtained directly from the participant's physician when the SC contacts the physician during follow-up of a positive screening exam. Depending on the extent of the information available and the physician's preference, the requested information may be obtained either verbally by phone or via written documentation. The physician diagnosis can be from a source other than the original diagnosing physician as long as the source states the physician's original diagnosis. One example is a progress note written by a follow-up physician. A pathology report documenting a benign condition is also an appropriate source.

11. **ICD-9-CM Classification of Diagnosis:** This section is to be used to record all diagnoses other than primary lung cancer. All specified diagnoses must be classified according to ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification). ICD-9-CM coding for the Lung Screening Study must be consistent with the national ICD-9-CM coding standards and should not be influenced by specific institutional coding philosophies.

> ***NOTE: If the diagnostic/staging procedures resulted in a diagnosis other than a Selected Condition, code this item "00000", complete item B.12 (Date of Diagnosis) with the resulting diagnosis date, and leave Item B.13 (Nosologist/Abstractor ID) blank.***

Cancer other than lung and Neoplasm of uncertain behavior – origin other than lung: For diagnoses of cancer other than lung and neoplasm of uncertain behavior, Item B.11 must be completed by a nosologist (a trained medical coder) who should record his/her four-digit ID# in the space provided. The nosologist should enter the five-digit ICD-9-CM classification in the space provided.

Selected Conditions: If the result of diagnostic/staging procedures was a selected condition, the abstractor should enter the ICD-9-CM code listed below for the condition. The following list identifies the selected conditions that should be documented. This item may be completed by an abstractor who should record his/her four digit ID# in the space provided (Item B. 13, Nosologist/Abstractor ID).

Selected Condition	Corresponding ICD-9-CM Codes
Atypical adenomatous hyperplasia	235.7
Squamous dysplasia	235.7
Diffuse Idiopathic Pulmonary Neuroendocrine hyperplasia	235.7
Carcinoma in situ (lung)	231.2
Asthma	493.9
Aspergillosis	117.3
Candida	112.4
Chronic obstructive lung disease (COPD):	
COPD without emphysema	496
COPD with emphysema	496.0
Coccidioidomycosis	114.5
Cryptococcosis	117.5
Emphysema	492.8
Fungal infection of the lung, NOS	117
Granuloma	515
Hamartoma	759.6
Histoplasmosis	115.0
Other Mycobacterium of the lung	031.0
Pneumonia	486
Sarcoidosis	135
Solitary lung nodule	518.89
Tuberculosis	011

Multiple Specified Diagnoses: If the result of the diagnostic evaluation was a cancer other than the lung and a selected medical condition, record the selected medical condition in the space for the ICD-9-CM code. The diagnosis of the other cancer must be recorded in Item B.14, Comments as illustrated in the following example:

If the result of diagnostic evaluation is granuloma as well as a bladder cancer, record the specified code for granuloma in the space for the ICD-9-CM code. The bladder cancer should be recorded in Comments as noted below:

Item B.14, Comments:

Item #	Comments
B.11	ICD-9-CM code for non-lung cancer is 188.9

If more than one selected condition results from the diagnostic evaluation, the corresponding ICD-9-CM codes should be recorded in Item B.14, Comments. Begin your statement in Comments with the verbatim as recorded in the following example:

Item B.14, Comments:

Item #	Comments
B.11	Additional ICD-9-CM code(s) for selected condition(s) are…

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12. Date of Diagnosis: Record the month, day, and year of the diagnosis recorded in Item B.11.

- If additional selected conditions were recorded in B.14: Comments for ICD-9-CM Classification of Physician Diagnosis, the Date of Diagnosis for these conditions should also be recorded in Comments. Begin your statement in Comments with the verbatim as recorded in the following example:

  Item B.14, Comments:

Item #	Comments
B.12	Date of Diagnosis for additional selected condition(s) is/are…

- In the situation in which no diagnostic evaluation procedures were performed, following a positive screening chest X-ray or spiral CT exam (i.e., when Item A.7: Did participant undergo diagnostic procedures? is coded "No, physician report," or "No, participant self-report"), record the date on which the physician made the decision not to do follow-up (for physician or SC report) or the date the participant informed the SC of his/her physician's decision not to do follow-up (for participant self-report).

- Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.

If the exact date of diagnosis cannot be determined from the record, year and month can usually be assessed. In this situation, record the exact month and year and the day as "99". Zero fill month and day, and record two digits for year. For any portion of the date that is unknown, record "9's." If there is no information for physician diagnosis, or if there is no information because the participant discontinued the diagnostic evaluation process, record "9's."

13. Nosologist/Abstractor ID#: The nosologist or abstractor completing Item B.11 should enter his/her ID number here.

14. Comments: Use this section to record any overflow information. Discrepant information should not be recorded in Comments. If an item being abstracted has conflicting or discrepant information, the SC Coordinator and/or the Principal Investigator should review the discrepant information for the appropriate coding decision prior to calling the CC.

If there are no additional comments, check the box next to "No." If there are additional comments, check the box next to "Yes," then record the comments as follows:

- First enter the item number indicating the item to which the comments are related, record the comments in the space provided to the right of the item number.

- Throughout these specifications, standard phrases are given to preface comments so they will be easier to locate during analysis. *Please use these phrases at the beginning of the comments, if applicable.*

- Place an asterisk next to the item number being referenced in the main body of the DE.

- If more space is needed, check the box next to "Continued," and record additional comments on a Comments Continuation Form (CCF).

Part C: Primary Lung Cancer Diagnosis Information:

This section documents all relevant information pertaining to a primary lung cancer diagnosis. Every attempt should be made to complete this form in a timely manner. For participants who have a positive screening exam, the DE should be completed within six months of the positive screening result. If specific items cannot be completed within the six month time frame (i.e., awaiting access to photocopy a form or awaiting TNM staging by the Tumor or Cancer Registrar), those items should be left blank; collect information concerning procedures that occurred on or before the date of conclusive diagnosis (including staging) or on or before May 1, 2001, whichever comes first.

If the participant was diagnosed with more than one primary lung cancer, record information about the first primary (chronologically by date of diagnosis) in Part C. For all subsequent primaries use another DE form (refer to instructions for Item A.4). If more than one primary was diagnosed on the first date of diagnosis, record information about the most advanced cancer diagnosed on that day in Part C, and use additional DE forms for any other cancers diagnosed on that day.

15. Date of Primary Lung Cancer Diagnosis: Record the month, day, and year of the primary lung cancer diagnosis that was confirmed by pathology/histopathology or cytology/cytopathology report. This is the date on the report that the actual procedure (biopsy, surgery, aspiration of cells, etc.) was performed that confirmed this primary lung cancer diagnosis.

Operative reports are generally more accurate for date of procedure than surgical pathology reports, so in the case of a discrepancy, record the date of procedure from the operative report.

In the rare situation in which primary lung cancer was diagnosed by clinical examination only and not histologically or cytologically, the date of first lung cancer diagnosis is the date of the clinical examination that diagnosed the cancer.

If there are multiple reports that confirmed this primary cancer, *record the earliest date available that has an adequate pathology specimen*. The earliest definitive procedure that diagnosed the cancer should be recorded, even if it is not the most complete picture of the cancer.

Zero fill month and day, and record two digits for year. Month and year of primary lung cancer diagnosis must be known, however, if day is unknown, record "99."

16. Photocopy of Report Confirming Primary Lung Cancer: The purpose of this item is to document that the pathology/histopathology report (or cytology/cytopathology report if a pathology report is not available) that confirmed the primary lung cancer has been photocopied and attached to the DE.

- If there are multiple pathology reports confirming this primary lung cancer, the photocopy should be of the *first* pathology or cytology report which was the source for recording the date of the primary lung cancer diagnosis recorded in Item C.15, and the ICD-O-2 code recorded in Item C.18. If the Date of Primary Lung Cancer Diagnosis and the ICD-O-2 Cancer Classification came from different reports, attach copies of both reports used to code Items C.15 and C.18.

- A situation may arise in which an institution does not allow the photocopying of records. Every reasonable attempt should be made to obtain permission to photocopy the pathology or cytology report since it is a critical end-point of the screening trial. If special permission or approval is required, the abstractor should work with the SC Coordinator/Principal Investigator to obtain the necessary approval. If this item cannot be completed in a timely manner, check "Report exists but cannot be obtained."

Check the box to indicate whether a photocopy of the pathology or cytology report is available as follows:

No Report: There is no pathology or cytology report in the medical record. This would include the rare occasion where primary lung cancer was diagnosed by clinical examination, and not histologically or cytologically confirmed. In this situation, Item C.17, Verbatim Description of Primary Lung Cancer Diagnosis, must be completed.

Pathology/Histopathology: The pathology report is available and a photocopy has been obtained and attached to the DE. The photocopy should be labeled with the PID, titled "DE/Pathology Report," and inserted into the participant's folder.

Cytology/Cytopathology: The cytology report is available and a photocopy has been obtained and attached to the Medical Record Abstract-DE Form. The photocopy should be labeled with the PID, titled "Medical Record Abstract-DE/Cytology Report," and inserted into the participant's folder.

Report exists but cannot be obtained: The pathology or cytology report exists in the medical record, but a photocopy cannot be obtained. Place an asterisk by Item C.16, and provide a detailed explanation in the Comments section (B.14) of why the pathology or cytology report cannot be obtained. In this situation, Item C.17, Verbatim Description of Primary Lung Cancer Diagnosis, must be completed. Begin your statement in Comments with the verbatim as recorded in the following example:

Item B.14, Comments:

Item #	Comments
C.16	Pathology or cytology report cannot be obtained because…

17. Verbatim Description of Primary Lung Cancer Diagnosis: This item is concerned with the actual physician diagnosis of primary lung cancer. <u>This item is optional except in the following situations:</u>

- the diagnosis is based on clinical examination and not pathology; or

- the SC is unable to obtain a copy of the pathology or cytology report that corresponds to the ICD-O-2 code in Item C.18.

Record the verbatim description of the primary lung cancer diagnosis from the pathology/histopathology report (or cytology/cytopathology report if a pathology report is not available). The verbatim description should come from the diagnosis section of the *earliest* (chronological) pathology report (or cytology report if the pathology report is not available) that had an adequate specimen and that confirms the cancer diagnosis.

- Occasionally, the diagnosis section will say "see above" or "see microscopic." In this situation record verbatim all of the information from the appropriate section of the report that pertains to the cancer diagnosis.

- Do not record any information about metastases or recurrent cancer.

- Do not record any information about benign conditions listed in the diagnosis section of the pathology or cytology report.

18. ICD-O-2 Cancer Classification: This item is for classifying the physician diagnosis of the primary lung cancer according to ICD-O-2 (International Classification of Diseases for Oncology, Second edition, 1990).

NOTE: This item is to be completed by a Tumor Registrar who is a Certified Tumor Registrar (CTR) or CTR-eligible individual.

The CTR or CTR-eligible individual should code the ten digit ICD-O-2 classification in the space provided beneath "Topography", "Morphology", "Behavior", and "Grade". The CTR or CTR-eligible individual should also record his/her four-digit ID# in the space provided.

- The ICD-O-2 code should reflect the diagnosis from the *earliest* (chronological) pathology report, that has an adequate specimen, (or cytology report if the pathology report is not available) which confirms the cancer diagnosis. The earliest definitive procedure that diagnosed the cancer should be recorded, even if it is not the most complete picture of the cancer. This should be the same report that was used as a source for the date of diagnosis in Item C.15.

- If the record clearly indicates that primary lung cancer was confirmed by a pathology or cytology report, but the report is not available, code the diagnosis from other available documents, (i.e. physician's notes, progress reports, etc.) that reference the earliest procedure from an adequate specimen. Place an asterisk by Item C.18, and indicate in the Comments section the source of the diagnosis. Begin your statement in Comments with the verbatim as recorded in the following example:

Item B.14, Comments:

Item #	Comments
C.18	Pathology/cytology report not available. Source of diagnosis is…

- If the primary lung cancer was diagnosed by clinical examination only, code the diagnosis using the report from the clinical examination form, which diagnosed the cancer. Using the clinical examination form, complete as much of C.18 as is known.

- The ICD-O-2 cancer classification should be entered by the CTR or CTR-eligible individual regardless of whether the ICD-O-2 code is available in the medical record.

19. Primary Tumor Location: This item is to document the site of origin of the malignant lung tumor, as determined by a surgical report, pathology report, or radiology report. Both Items 19a and 19b must be completed to describe the location of the lung tumor. In Item 19a, check all boxes that correspond to the site of origin. Item 19b should have only one box checked. If the primary tumor location is unknown or not mentioned in the record, check the box next to "Unknown."

20. Histopathologic Type for Primary Lung Cancer: This item is to be completed only by a CTR or CTR-eligible individual. This item is to document the histopathologic type of the primary lung cancer. This refers to the type of cell comprising the tumor, usually determined by the pathologist from a tissue specimen. This information can be obtained from the pathology report or cytology report of the bronchial washing/brushing that confirmed the primary lung cancer and collected the most tissue. If neither a pathology report nor a cytology report is available, this information may be found in the discharge summary, or an operative report. If the histopathologic type is obtained from a source other than the pathology report, place an asterisk by Item C.20, and record the source of the information in the Comments section (Item B.14). Begin your statement in Comments with the verbatim as recorded in the following example:

Item B.14, Comments:

Item #	Comments
C.20	Source of histopathologic type of lesion is…

- If the cancer has two different histopathologic types, the diagnosis is usually based on the predominant type. This should be stated in the pathology report. In this situation, record the predominant histopathologic type. If the pathology report does not indicate a predominant type, leave Item C.20 blank, place an asterisk by Item C.20, and record in the Comments section. Begin your statement in Comments with the verbatim as recorded in the following example:

  Item B.14, Comments

Item #	Comments
C.20	Histopathologic type of lesion is…

- The CTR or CTR-eligible individual should select the general category into which the result fits rather than using "Other" to list a more detailed result. For example, if the medical record stated "adenocarcinoma arising in tubulovillous carcinoma" this should be coded as "adenocarcinoma" rather than "Other".

- In general:

  - If the carcinoma is invasive, it is not in situ
  - If hyperplasia is noted, the carcinoma is not in situ
  - If the carcinoma is noninvasive, it is in situ.

  Check the box corresponding to the histopathologic type of the primary lung cancer. If the histopathologic type is unknown or not available in the record, check the box for "Unknown."

21. Histopathologic Grade for Primary Lung Cancer: This item is to be completed only by a CTR or CTR-eligible individual. This item documents the histopathologic grade of the primary lung cancer. Grade refers to a system of classifying certain characteristics of the cell. This information can be obtained directly from the pathology report, which collected the most tissue, a cytology report, a TNM form, a staging classification form, the discharge summary, or from doctor's notes.

- If the medical record states two types of histopathologic grades, or a range of grades, record the most severe type. "Well differentiated" is the least severe type and "undifferentiated" is the most severe type. The most severe grade should be recorded from the primary site. Do not record the most severe grade from the metastatic site.

Check the box corresponding to the histopathologic grade of the primary lung cancer. Check the box for "Unknown" when there is no indication in the record of the histopathologic grade.

22. TNM Staging for Primary Lung Cancer: This item is to be completed by a CTR or CTR-eligible individual. A CTR or CTR-eligible individual should use all relevant information from the patient's medical record to assign the TNM stage. If an abstractor or nosologist happens to be a CTR or CTR-eligible individual also, then the abstractor or nosologist can complete TNM stage.

This item refers to the TNM or AJCC (American Joint Committee on Cancer) staging system. TNM staging describes the anatomic extent of disease based on three components:

(1) the extent of the primary tumor (T),

(2) the absence or presence and extent of regional lymph node metastases (N), and

(3) the absence or presence of distant metastases (M).

The addition of numbers to these three components indicates the extent of the malignant disease, thus showing progressive increase in tumor size or involvement.

If a participant receives neoadjuvant therapy prior to surgical resection, abstractors should do TNM Clinical Staging of the Primary Cancer, and complete item C.22a. Then record Item C.22b, TNM Pathologic Staging, using surgical pathology. In this situation TNM Pathologic Staging should be recorded as follows:

- Complete Item C.22b TNM Pathologic Staging using the surgical pathology report.
- Place an asterisk next to the item number and go to the Comments section in Item B.14.
- Record the item number in the left margin of the Comments section and begin with the phrase, "ypT_N_M", including the appropriate numerical stage of the carcinoma which was recorded in Item C.22b, TNM pathologic Staging. "y" is a TNM descriptor that indicates that staging was performed during or following multi-modal therapy and the "p" indicates pathologic staging. After the appropriate information has been included in the "ypTNM" format, briefly state what treatment was received prior to surgery.

The AJCC Manual for Staging of Cancer provides the minimum requirements for clinical and pathologic staging. A list of relevant documentation, based on those requirements can be found below.

Note: The 5th Edition of the AJCC manual was published in January 1998. This latest edition should be used to code all diagnosed cancers.

General Guidelines for NX vs. N0 and MX vs. M0:

The X category should be used when involvement of regional lymph nodes or distant metastatic sites was not evaluated or could not be evaluated. It is not sufficient to assume that an evaluation would have been negative (or positive). If there is a statement in the record documenting the physician's assessment of regional lymph nodes and/or metastatic sites as negative or not involved, without physical examination, imaging or other diagnostic procedures, this may be used to assign 0 rather than X. The use of category 0, as in N0 or M0, means that no involvement was found after some type of evaluation including appropriate workup and/or the physician's clinical impression.

NOTE: SCs should photocopy any documents from medical records that are used for TNM staging, and keep these with the participant's file.

a. TNM Clinical Staging (To be completed only by a CTR or CTR-eligible individual.)

If both clinical and pathological staging are available, both should be recorded. Clinical staging is based on the assessment of the anatomic extent of disease. All information available prior to the first definitive treatment of primary lung cancer may be used for TNM clinical staging. Relevant documentation that is suggested to assign clinical staging includes:

- Physical examination and medical history;
- Imaging procedures;
- Endoscopy, including bronchoscopy, esophagoscopy, mediastinoscopy, thoracentesis, and thoracoscopy; and
- Other tests designed to demonstrate extrathoracic metastasis and regional extension.

Check the box to indicate whether the TNM clinical staging is available as follows:

Yes: If the TNM clinical staging is available, or at least some part of it is available, check the box for "Yes" and then check the boxes corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, check the box next to "Not available" in the column(s) for which the code is not available.

No: If no part of the TNM clinical staging is available, then check the box for "No" and skip to C.22b, TNM Pathologic Staging.

b. TNM Pathologic Staging (To be completed only by a CTR or CTR-eligible individual.)

Relevant documentation which is necessary to assign pathologic staging includes:

- Any data for clinical staging;
- Thoracotomy; and
- Examination of the resected specimen, including lymph nodes.

Check the box to indicate whether the TNM pathologic staging is available as follows:

Yes: If the TNM pathologic staging is available, or at least some part of it is available, check the box for "Yes" and then check the boxes corresponding to the Primary Tumor (T) code, the Nodal Involvement (N) code, and the Distant Metastases (M) code. If the code for T, N, or M is not available, check the box next to "Not available" in the column(s) for which the code is not available.

No: If no part of the TNM pathologic staging is available, then check the box for "No" and skip to Item C.23, Record Stage.

23. Record Stage: If TNM Pathologic Staging is available, this item must be skipped. If Item C.22.b (TNM Pathologic Staging) is coded "No," or "Yes", with information missing for the "T," "N," or "M," complete Item C.23. This item is to document the stage of disease for primary lung cancer using a system other than TNM. There are three stage classifications provided for lung cancer: "Stage Only," "VALSCG" (Veterans Administration Lung Cancer Study Group) for small cell lung cancer only, and "Summary Staging."

- If information about one or more of the stage classifications is not available in the medical record, it is not necessary to try to obtain it from another source.

- If a stage classification other than those provided, and other than TNM, is available in the record, leave Item C.23 blank, place an asterisk beside Item C.23, and record in the Comments section the staging information found in the record. Begin your statement in Comments with the verbatim as recorded in the following example:

Item B.14, Comments

Item #	Comments
C.23	Other Stage of Classification is_____. Stage = _____.

Check the box to indicate whether stage of disease is available as follows:

Yes: If "Stage Only," "VALCSG," and/or "Summary Staging" is available, check the box for "Yes" and then check the boxes corresponding to the code for each. If stage of disease is not available for any particular classification, check the box next to "Not available" in the appropriate column.

No: If *none* of the three stage classifications, "Stage Only," "VALCSG," or "Summary Staging" is available in the record, check the box for "No."

- If no stage of disease information is available, it is not necessary for the abstractor to obtain it from another source. Also, the abstractor should not attempt to code stage of disease unless s/he is a Certified Tumor Registrar (CTR) or CTR-eligible. If the abstractor is a CTR, or is CTR-eligible *and* has all of the necessary documentation for determining the stage of disease, then s/he may code stage of disease and record it following the guidelines above.