DATA USER'S MANUAL

National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

MDE Version 7.0
Effective 01/01/2019

Manual Revised August 2019

Centers for Disease Control and Prevention
Coordinating Center for Health Promotion
National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control

Public reporting burden of this collection of information is estimated to average 4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, GA 30333; ATTN: PRA (0920-0571).
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Introduction

This manual was written by the Centers for Disease Control and Prevention (CDC) to centralize the information needed to produce data for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). One goal of the manual is to provide the technical information necessary for the Programs to produce the Minimum Data Elements (MDE). Another goal is to highlight the technical assistance provided to the Programs by the CDC and IMS, Inc. A common goal of the CDC and the Programs is to produce data that are timely, complete, and accurate so that we can better serve the women of the NBCCEDP, and prepare reports for stakeholders.

The intended audience for the Data User’s Manual is the Program staff responsible for the collection and aggregation of the Program data. It is divided into the following three chapters:

Chapter 1  **Data Management**

This chapter contains the dates that the MDEs are to be submitted to the CDC, along with the technical requirements for submission. This chapter also includes a brief description of each MDE submission feedback report.

Chapter 2  **MDEs**

This chapter contains a detailed description of each MDE data item, along with the data record format.

Chapter 3  **Tools and Resources**

This chapter includes helpful material related to breast and cervical cancer screening. The NBCCEDP Policy on Inclusion of Data in the MDEs, CDC-Based Program Policies and the Data Quality Indicator Guide, NBCCEDP Timeliness and Adequacy Algorithm, NBCCEDP related acronyms and glossary are included in this section.
Chapter 1

Data Management
What

MDE data and accompanying Submission Narrative are submitted semi-annually to the CDC through its Data Management Contractor, Information Management Services, Inc. (IMS), on April 15 and October 15. Each MDE submission should include cumulative data from the date the Program began screening through the screening cut-off date. Each submission dataset will replace the previous submission in its entirety.

The screening cutoff date is three and a half months prior to the submission date. For example, if the data are due to be submitted on 10/15/2019, then the data should cover screening tests performed from the onset of the screening Program through 6/30/2019. The date used for the cut-off should be the date of the first test in the cycle.

The three and a half month reporting lag allows time to collect and enter the data. An additional six months is allowed to collect and report diagnostic follow-up and outcomes of patients with abnormal screening results. The diagnostic cut-off date occurs nine and a half months before the submission date. Records for patients whose screenings occurred after the diagnostic cut-off date are not expected to have complete diagnostic and treatment information. These records should be completed in the next submission.

### MDE Submission and Cut-off Dates

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 months</td>
<td>Submission due date Semi-annually: April 15, October 15</td>
</tr>
<tr>
<td>6 months</td>
<td>Screening cut-off date 3.5 months prior to submission due date</td>
</tr>
<tr>
<td></td>
<td>All screens prior to this date are reported in MDEs</td>
</tr>
<tr>
<td></td>
<td>Diagnostic cutoff date 9.5 months prior to submission due date</td>
</tr>
<tr>
<td></td>
<td>All screens prior to this date are expected to have complete screening and diagnostic information</td>
</tr>
<tr>
<td></td>
<td>“Core Indicators” are evaluated on the 12 months of data immediately preceding the diagnostic cut-off date</td>
</tr>
</tbody>
</table>
MDE Data Submission

When

All MDE submission files are to be submitted according to the schedule below.

<table>
<thead>
<tr>
<th>Submission Due Date</th>
<th>Screening Cut-off Date</th>
<th>Core Indicator Timeframe Evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 15, 2019</td>
<td>June 30, 2019</td>
<td>1/1/2018 – 12/31/2018</td>
</tr>
<tr>
<td>April 15, 2020</td>
<td>December 31, 2019</td>
<td>7/1/2018 – 6/30/2019</td>
</tr>
<tr>
<td>April 15, 2021</td>
<td>December 31, 2020</td>
<td>7/1/2019 – 6/30/2020</td>
</tr>
<tr>
<td>October 15, 2021</td>
<td>June 30, 2021</td>
<td>1/1/2020 – 12/31/2020</td>
</tr>
<tr>
<td>April 15, 2022</td>
<td>December 31, 2021</td>
<td>7/1/2020 – 6/30/2021</td>
</tr>
</tbody>
</table>

All submission files should be received by close of business on the submission due date. If the due date falls on a weekend, then the files should be received by close of business on the first business day after the submission due date.

How

All MDE submission files must be submitted electronically using the secure www.nbccedp.org website. When an MDE submission is due, the MDE data must be extracted from your system and converted to the standardized MDE format.

**MDE File Format:** The MDE file consists of fixed length records in an ASCII format. In MDE version 7.0, each record has 231 characters of screening, diagnosis and treatment information and a 1 character end-of-record delimiter for a total of 232 characters per record. The end-of-record delimiter should be a “carriage return-line feed”. A detailed description of the MDE items in each record is included in Chapter 2.

**MDE File Compression:** IMS and the CDC require the use of compression software such as WinZip, Gzip or 7-Zip to compress the MDE data file prior to submission.
MDE Data Submission

**MDE File Naming Convention:** The compressed MDE data file (*.ZIP, *.GZ or *.7z) should be submitted using the following naming convention:

YPMMYYVV.EXT

- **YP** = Your Program abbreviation
- **MM** = Month of submission due date, with leading zeroes (10 = October)
- **YY** = Year of submission due date (19 = 2019)
- **VV** = MDE version number (70 = MDE version 7.0)
- **EXT** = Extension of the compressed MDE data file (*.ZIP, *.GZ or *.7z)

Using the example above, if a compressed ZIP file archive is submitted to IMS, it should have the following name: YP101970.ZIP. The ZIP file archive should contain an ASCII text file called YP101970.TXT. Please do not include other files, such as the Submission Narrative or supporting documents in the compressed MDE file archive. Those files should be posted separately.

**Updates and Corrections**

For each data submission, Programs are required to submit a *cumulative* data set through the screening cut-off date. Therefore, if any changes or updates to a particular record occur between submissions, these changes will be incorporated within the next MDE file.

**MDE Edits Application**

Programs must run their data through the edit routine supplied by IMS prior to submission. The MDE Edits Application performs basic validation routines and reports on invalid values, missing items, and cross-item edits. The MDE Edits Application can only be run on an MDE file. The MDE file must first be sorted by the unique Patient ID. Programs are reminded that data should be edited on a routine basis (weekly, monthly, etc.), not solely at the time of submission. An explanation of problem areas should be highlighted in the Submission Narrative. A current version of the MDE Edits Application is available to download from the [www.nbccedp.org](http://www.nbccedp.org) website.

**Submission Narrative**

Each Program’s MDE data are regularly reviewed by the CDC, IMS, and Program staff during data conference calls. Often, questions from the CDC or IMS arise from these reviews and will require a Program to make modifications to the clinical data, the data collection system, or data extraction procedures prior to the next MDE submission. The Submission Narrative provides a
structured way for Programs to report responses to these questions or data modifications.

**Submission Narrative Format**

The Submission Narrative has two main sections. Section I provides a place for Programs to respond to the Action Items. Action items are written questions from the CDC and IMS based on a review of the previous MDE submission. Section II is comprised of six standard questions that require Programs to do a prospective review of their MDE data prior to submitting to IMS. It is expected that Programs should have the capability to review and manage their data, and should not rely solely on the MDE submission feedback provided by the CDC and IMS. Additional questions regarding data management staffing changes or data collection software changes are also included. A response to each of the questions is required, even if the response is “N/A-Not Applicable”.

A copy of the MDE Submission Narrative Guidelines can be found in Chapter 3, Appendix 5 of this Data User’s Manual. An electronic copy, along with an example of a completed narrative can also be found on the [www.nbcccedp.org](http://www.nbcccedp.org) website.

A Submission Narrative must be submitted electronically with each MDE data file using the secure [www.nbcccedp.org](http://www.nbcccedp.org) website.

**Submission Narrative Standards**

The narrative file should be created in *.doc, *.docx or *.pdf format and submitted using the following naming convention:

```
YPMMYY-NARRATIVE.EXT
```

YP = Your Program abbreviation  
MM = Month of submission due date, with leading zeroes (10 = October)  
YY = Year of submission due date (19 = 2019)  
EXT = Extension of the narrative file type (*.doc, *.docx or *.pdf)

For example, if the submission narrative file is submitted to IMS in PDF format, it should have the following name: YP1019-narrative.pdf. The narrative file should be submitted separately from the MDE data file.
The MDE Submission Process

There are six steps in the MDE Submission Process that repeat semi-annually:

<table>
<thead>
<tr>
<th>Semi-annual Timeline</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>April October</td>
<td>Programs prepare and submit an MDE file and Submission Narrative on April 15 and October 15.</td>
</tr>
<tr>
<td>June December</td>
<td>IMS creates an analysis file that is provided to the CDC, within a specified time frame, for review and approval.</td>
</tr>
<tr>
<td>July January</td>
<td>IMS generates feedback reports which are reviewed and posted to the <a href="http://www.nbccedp.org">www.nbccedp.org</a> website within a specified time frame.</td>
</tr>
<tr>
<td>August February</td>
<td>MDE Data Review Calls are held within approximately one month of the posting of the feedback reports. Data Notes, prepared by the IMS Technical Consultant, are posted three business days in advance of the scheduled call.</td>
</tr>
<tr>
<td>August February</td>
<td>The IMS Technical Consultant sends Action Items to the Program Consultant and the Program within five business days after a data call.</td>
</tr>
<tr>
<td>September March</td>
<td>The Program investigates Action Items and completes responses in Sections I and II of the Submission Narrative and submits to IMS with the next MDE submission.</td>
</tr>
</tbody>
</table>

Once the MDE data are received at IMS, they are reviewed. This review includes the MDE Edits as well as a comparison with the previous submission using key items. A SAS analysis file is then created to standardize data and eliminate duplicate screening results. A series of feedback reports are generated to assess the completeness and accuracy of these data, as well as to document the percentage of abnormal screening results that have complete diagnostic and treatment data. These data are assessed to determine progress in meeting Program goals.

Once the feedback reports are reviewed, the Program will participate in a conference call with the CDC and IMS to discuss specific data issues. Following
the data call a set of Action Items is prepared by the Program’s IMS Technical Consultant. These Action Items are questions that must be answered by the Program in their next submission narrative.

**MDE Submission Feedback Loop**

![MDE Submission Feedback Loop Diagram]

**Software Selection**

Each Program has a difficult task in deciding which computer software to use to manage the data for the NBCCEDP. The decision must balance the unique needs of the Program, the cost of developing an in-house system, as well as the suitability of available software. Options other than developing a custom in-house system would include adding on to an existing health system in your Program, purchasing software from vendors that have developed other NBCCEDP systems, or using the CDC-provided CaST System. The Cancer Screening and Tracking (CaST) System is a database management system, used to track women screened for breast and cervical cancer. It contains the data items required for the MDEs.

If for any reason a Program chooses to convert their existing data system to a different software package, it is strongly recommended that a test data submission be sent to IMS for review. The test submission should be done well in advance of an MDE submission deadline. It is strongly recommended that Programs provide a test submission at least one month prior to the standard semi-annual MDE submission. The IMS Technical Consultant should be notified prior to sending the test data. Similarly, it is strongly recommended that revised data forms be sent to CDC and IMS for data management and clinical review prior to finalizing.
Understanding the MDEs

Structure of the MDEs

The MDEs consist of four distinct components: the All Patients Sections, the Cervical Final Diagnosis and Treatment Sections, the Breast Final Diagnosis and Treatment Sections, and the Cancer Registry Data Sections.

All Patients Sections

The All Patients Sections are completed for each MDE record. MDE records should be created when any screening, diagnostic procedure, or patient navigation is paid for with NBCCEDP funds. These sections include patient ID, patient demographic information, and screening results for Pap tests, HPV tests, mammograms, screening MRI, and clinical breast exams. If a woman does not have a Pap test or mammogram, the appropriate values should be used for the "Indication" items. Tables have been included in this chapter to help outline how to complete cervical data when only a breast exam was performed, and vice versa.

Cervical Final Diagnosis and Treatment Sections

While the All Patients Sections are completed for each MDE record, the Cervical Final Diagnosis and Treatment Sections are completed when there is an abnormal pelvic exam, abnormal Pap test screening results, abnormal HPV test results, or other concerns that require immediate diagnostic work-up. These sections consist of a final diagnosis and treatment data for cervical cancers.

When reporting final diagnoses, it is important to remember that the MDE record is not intended to directly reflect the clinical chart. A Program’s data collection system should be designed to collect more detailed information than the MDEs.

Breast Final Diagnosis and Treatment Sections

The Breast Final Diagnosis and Treatment Sections are completed when there is an abnormal CBE, abnormal mammogram result or other concerns that require immediate diagnostic work-up. These sections consist of a final diagnosis and treatment data for breast cancer cases.

When reporting final diagnoses, it is important to remember that the MDE record is not intended to directly reflect the clinical chart. A Program’s data collection system should be designed to collect more detailed information than the MDEs.
Understanding the MDEs

**Cancer Registry Data Sections**

The Cervical and Breast Cancer Registry Data Sections allow Programs to standardize the collection of stage data and to improve the quality of data in both the State Cancer Registry and the NBCCEDP Program. The cancer stage at diagnosis and other clinical variables are standardized to one classification scheme, or data source, in Version 7.0.

**Summary**

It is important that the MDE sections are completed appropriately. The All Patients Sections are completed for every MDE record. The Cervical Final Diagnosis and Treatment Sections and the Breast Final Diagnosis and Treatment Sections are completed for those women where additional diagnostic procedures were necessary to evaluate the initial screening result and rule out cancer. Since this is a relatively small number of women, most of the MDE records will only contain the All Patients Sections, and the other sections will be blank. If the Final Diagnosis and Treatment Sections are necessary, the final diagnosis, diagnostic disposition, and date of diagnostic disposition must be completed for each MDE record. Based on the final diagnosis, the treatment and Cancer Registry items may also be required. Please see the Item Descriptions for Cervical Final Diagnosis and Breast Final Diagnosis for more details.

**MDE Data for Women Receiving Patient Navigation Only**

Grantees should collect and report data on women who receive only NBCCEDP-funded patient navigation (PN) services. These women receive NBCCEDP-funded PN but do NOT receive NBCCEDP-funded screening or diagnostic services. Grantees are required to submit an abbreviated MDE record on navigated-only women who complete screening and/or diagnostic services.

**Patient Navigation Definition**

The current NBCCEDP policy outlines a number of activities ‘defining’ patient navigation (see: NBCCEDP Policy Manual.) These include: assessment of client barriers, client education and support, resolution of client barriers, client tracking and follow-up, a minimum of two contacts with the client, and collection of data to assess client completion of screening and/or diagnostics. The CDC considers case management for women with abnormal screening results a type of patient navigation, as long as the aforementioned activities are performed.
Understanding the MDEs

Eligibility for NBCCEDP-funded, navigation-only services

Patient navigation services may be provided to clients enrolled in the NBCCEDP as well as those who have other resources (e.g., insurance) to pay for screening and diagnostic services. Detailed eligibility guidelines are available in the NBCCEDP Policy Manual, available on the www.nbccedp.org website.

Submitting MDE records for Women Receiving Patient Navigation Only

MDE Item 3.01 is required for all records and used to capture whether NBCCEDP-funded patient navigation services were provided by the grantee. If patient navigation is delivered (consistent with CDC policy) using NBCCEDP funds to support the navigation (e.g. reimbursement fee-for-service, paid for staff delivering PN), select ‘1’ (Yes.) A response of ‘2’ (No) should be selected if NBCCEDP funds were not used or patient navigation was not delivered. Historical data should be coded as ‘3’ Unknown.

“PN Only” records are those where MDE Item 3.01 (Patient Navigation Paid by NBCCEDP Funds) is coded as (1) Yes and Item 4.04 (Cervical Service Paid by NBCCEDP Funds) and Item 5.02 (Breast Service Paid by NBCCEDP Funds) are coded as (2) No. These records will be ‘abbreviated’ MDE records. Demographic data will be collected on these women. Test results, test dates, whether tests were paid for using NBCCEDP funds, and final diagnosis data will also be reported in the abbreviated MDE record. See Appendix 7 for detailed specifications on required fields for abbreviated MDE records. Both abbreviated and full MDE records should be submitted in the same MDE file.

Screening Cycle Definition

To a clinician, a screening cycle is comprised of the patient’s screening and follow-up. To the Breast and Cervical Cancer Program, a screening cycle is the proper completion of the MDE record. A screening cycle begins with a Pap test, HPV test, mammogram, screening MRI, or clinical breast exam and ends, most of the time, with a normal screening result. In MDE terms, this means that only the All Patients Sections need to be completed. However, for a woman with an abnormal screening result, the screening cycle will not be complete until the final diagnosis and treatment data are complete. In MDE terms, this means that either the Cervical Final Diagnosis and Treatment Sections or Breast Final Diagnosis and Treatment Sections need to be completed for the screening cycle to be closed.
Understanding the MDEs

This standardization of reporting required by the screening cycle definition does not always fit the realities of clinical practice. For example:

Short Term Follow-up

Short term follow-up is defined as cases in which the provider decides that immediate diagnostic work-up is not needed, and there is a planned delay between the current and the subsequent visit for the woman. Short term follow-up begins a new cycle in the MDEs, as opposed to immediate diagnostic follow-up which is reported in the same MDE cycle with the screening test that indicated the need for immediate diagnostic evaluation.

Short term follow-up is defined by the provider’s intent. It is not the amount of time that passes between tests which is relevant, but rather the reason the time passed.

Often a clinician will recommend a repeat Pap test in 3 months based on a pelvic exam with questionable results. To the clinician, this is follow-up. In the MDEs, the repeat Pap test begins a new cycle.

Case 1: A woman comes in for a Pap test on 7/1/2012, the Pap result is negative, but the clinician finds the pelvic exam result to be suspicious and wants the woman to return in 3 months for a repeat Pap test. When the woman returned on 10/15/2012 both the Pelvic exam and Pap test were normal.

Record 1
All Patients Sections
4.07 = (1) Negative
4.09 = 07012012
4.13 = (2) Diagnostic Work-up not Planned
Cervical Final Diagnosis and Treatment sections are blank.

Record 2
All Patients Sections
4.07 = (1) Negative
4.09 = 10152012
4.13 = (2) Diagnostic Work-up not Planned
Cervical Final Diagnosis and Treatment sections are blank.

The same would hold true if a woman had a mammogram with a result of Benign and short term follow-up was recommended. The repeat mammogram would begin a new cycle.
It is not the amount of time that passes between tests, but rather the reason that the amount of time passed: was it on purpose or could the test have been done earlier? A planned delay, such as a clinician wanting some time to pass before re-evaluating would begin a new cycle. If the clinician wanted immediate diagnostic tests, but the tests were delayed by the woman or by a scheduling problem, then the tests are a continuation of the abnormal screening cycle.

Case 2: A woman had a mammogram on March 12, 2012. The mammogram result was Suspicious Abnormality. Her clinician recommended that she have an ultrasound in the next couple of days so they can rule out the possibility of cancer. The woman wanted a second opinion and did not receive her ultrasound until May 5, 2012. The result of that ultrasound was negative, it was only a cyst.

Record 1

*All Patients Sections*

5.07 = (4) Suspicious Abnormality
5.08 = 03122012
5.11 = (1) Additional procedures needed or planned

*Breast Final Diagnosis Section*

8.01 = (1) Work-up complete
8.02 = (3) Breast Cancer not diagnosed
8.03 = 05052012

**Same Initial Exam - Two Different Results**

This situation happens on the breast side. During a mammogram visit, both breasts are examined. In some instances, the result for one breast will be normal, while the result for the other breast may be abnormal, such as “Suspicious of Malignancy.” This only gets reported in the MDEs as one procedure. The most severe result (in this case Suspicious of Malignancy) should be reported in the MDEs.

The same would hold true for diagnostic procedures. For example, a woman may have a biopsy which is reported as both Lobular Carcinoma in situ and Invasive Breast Cancer. The most severe result (in this case Invasive Breast Cancer) should be reported in the MDEs as the Final Diagnosis.
Understanding the MDEs

**Pap tests Done at the Time of a Colposcopy**

In some cases, a woman has a screening Pap test that has an abnormal result and is referred for a colposcopy-directed biopsy. At the time of the colposcopy, the provider chooses to do a repeat Pap test. This Pap test, done at the time of colposcopy, is considered not clinically necessary, and should not be reported in the MDEs.

**Screening Follow-up vs. Surgical Follow-up**

A CBE that is done based on the recommendation that a woman return for short-term follow-up, based on a previous CBE or mammogram result, begins a new cycle. The intent of the CBE is for screening purposes.

A CBE that is done based on the recommendation that a woman return for surgical follow-up is NOT reported in the MDEs. The intent of this CBE is for surgical follow-up, not screening or diagnostic follow-up.

Good communication with your providers is necessary to deal with these circumstances. The intent of the MDE definitions is not to standardize clinical practice, but simply to standardize reporting so Program results can be meaningfully compared.

**Other Coding Scenarios**

**HPV and/or Pap Test Screenings**

In the case where a woman has a screening Pap test, and no HPV test was performed, the record should be coded as follows:

*Cervical Screening Information Section*
4.03 = (1) Screening
4.07 = Completed with Pap test result
4.09 = Completed with date of Pap test
4.10 = (3) Test not done

In the case where a woman has Pap and HPV co-testing, the record should be coded as follows:
Understanding the MDEs

*Cervical Screening Information Section*
4.03 = (1) Screening
4.07 = Completed with Pap test result
4.09 = Completed with date of Pap test
4.10 = (1) Co-Test/Screening
4.11 = Completed with HPV test result
4.12 = Completed with date of HPV test

In the case where a woman has a primary HPV test screening, the record should be coded as follows:

*Cervical Screening Information Section*
4.10 = (1) Co-Test/Screening
4.11 = Completed with HPV test result
4.12 = Completed with date of HPV test

If 4.11 = (4) Positive with positive genotyping: direct to colposcopy
4.03 = (4) No Pap
4.13 = (1) Diagnostic work-up planned

If 4.11 = (5) Positive with negative genotyping: direct to Pap test
4.03 = (6) Pap after primary HPV+
4.07 = Completed with Pap test result
4.09 = Completed with date of Pap test

*Screening High Risk Women for Breast Cancer*

Women at high risk for breast cancer are eligible for a screening MRI in addition to a screening mammogram. In these cases, the screening MRI may occur months after the mammogram, and should be reported in separate cycles.

**Record 1**

*Breast Screening Information Section*
5.01 = (1) Screening
5.04 = (1) Yes
5.05 = (9) Not done
5.06 = Blank
5.07 = Completed with mammogram test result
5.08 = Completed with date of mammogram
5.11 = (2) Additional procedures not needed or planned
Understanding the MDEs

Record 2

_Breast Screening Information Section_

5.01 = (4) No mammogram
5.04 = (1) Yes
5.05 = Completed with screening MRI result
5.06 = Completed with date of screening MRI
5.07 = Blank
5.08 = Blank

Reporting Breast and Cervical Data: Separate vs. Combined MDE Records

The screening cycles for the CBEs, Pap tests, HPV tests, screening MRIs, or mammograms can be reported in a variety of ways in the MDE record. It is important to note that the CDC does not evaluate comprehensive care (i.e. whether all procedures were performed at one time), but the CDC does evaluate quality of care (i.e. based on the result, was appropriate follow-up performed). Depending on your Program’s data system, you may choose to report the data in one of two ways:

**Combined Records**

The data for the major exams (Pap test, HPV test, CBE, mammogram, screening MRI) are reported all on one record. Often the Pap test and CBE are done during the same visit, however when there are no breast symptoms, the mammogram may not occur until several months later. It is perfectly acceptable to report all three exams on one MDE record, regardless of the delay.

When reporting data in a combined record, Programs will need to consider how to handle short term follow-up. For example, a woman is asked to return every 6 months for a Pap test, but her mammogram is performed annually. Which Pap test record will the data system associate the mammogram with? Programs need to be sure that they do not report duplicate screening data across MDE records for a woman.

**Separate Records**

Alternatively, programs may choose to report breast and cervical data on two different records. When reporting breast and cervical data separately, there will be a cervical record which reports data specific to cervical screening where the Indication for Initial Mammogram is coded as “5. No Breast Service” and a separate breast record where the Indication for Pap test is coded as “5. No Cervical Service”. Please see the tables that follow for guidance on how to complete an MDE record when separating breast and cervical records.
How to Complete Cervical Data in the Full MDE Record
When Only Breast Data are Provided

NOTE: When reporting only mammogram data, only the Previous Pap Test (item 4.01) and the Indication for Pap test (Item 4.03) fields need to be completed for the cervical screening data.

<table>
<thead>
<tr>
<th>ITEM NAME</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous Pap Test</td>
<td>(3) Unknown</td>
</tr>
<tr>
<td>Date of Previous Pap Test</td>
<td>Blank</td>
</tr>
<tr>
<td>Indication for Pap Test</td>
<td>(5) No cervical service</td>
</tr>
<tr>
<td>Cervical Service Paid by NBCCEDP Funds</td>
<td>Blank</td>
</tr>
<tr>
<td>High Risk for Cervical Cancer</td>
<td>Blank</td>
</tr>
<tr>
<td>Cervical Diagnostic Referral Date</td>
<td>Blank</td>
</tr>
<tr>
<td>Result of Pap Test</td>
<td>Blank</td>
</tr>
<tr>
<td>Other Pap Test Result</td>
<td>Blank</td>
</tr>
<tr>
<td>Date of Pap test</td>
<td>Blank</td>
</tr>
<tr>
<td>Indication for HPV Test</td>
<td>Blank</td>
</tr>
<tr>
<td>HPV Test Result</td>
<td>Blank</td>
</tr>
<tr>
<td>Date of HPV Test</td>
<td>Blank</td>
</tr>
<tr>
<td>Diagnostic Work-up Planned for Cervical Dysplasia or Cancer</td>
<td>Blank</td>
</tr>
<tr>
<td>Clinical Breast Exam (if reported with Pap record)</td>
<td>(5) Not performed</td>
</tr>
<tr>
<td>Date of Clinical Breast Exam (if reported with Pap record)</td>
<td>Blank</td>
</tr>
</tbody>
</table>

* NOTE: These rows are only relevant if you collect/report CBEs with Pap Test data. Clinical Breast Exam may have been done at time of a recent Pap test. Therefore CBE does not need to be repeated with the breast visit. When this occurs, CBE should be coded as (5) Not Performed. All other items in the All Patients Sections should be completed appropriately.
Understanding the MDEs

How to Complete Breast Data in the Full MDE Record
When Only Pap and/or HPV Test Data are Provided

NOTE: When reporting only cervical data, only the Indication for Initial Mammogram (Item 5.01) needs to be completed for breast screening data.

<table>
<thead>
<tr>
<th>ITEM NAME</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication for Initial Mammogram</td>
<td>(5) No breast service</td>
</tr>
<tr>
<td>Breast Service Paid by NBCCEDP Funds</td>
<td>Blank</td>
</tr>
<tr>
<td>Breast Diagnostic Referral Date</td>
<td>Blank</td>
</tr>
<tr>
<td>High Risk for Breast Cancer</td>
<td>Blank</td>
</tr>
<tr>
<td>Screening MRI Results</td>
<td>Blank</td>
</tr>
<tr>
<td>Date of Screening MRI</td>
<td>Blank</td>
</tr>
<tr>
<td>Initial Mammography Test Result</td>
<td>Blank</td>
</tr>
<tr>
<td>Date of Initial Mammogram</td>
<td>Blank</td>
</tr>
<tr>
<td>Clinical Breast Exam (if done with mammogram)</td>
<td>Blank</td>
</tr>
<tr>
<td>Date of Clinical Breast Exam (if done with mammogram)</td>
<td>Blank</td>
</tr>
<tr>
<td>Additional Procedures Needed to Complete Breast Cycle</td>
<td>Blank</td>
</tr>
</tbody>
</table>

* NOTE: Clinical Breast Exam may have been done at time of a recent mammogram. Therefore CBE does not need to be repeated with the cervical visit. When this occurs, CBE should be coded as Blank, as noted above. All other items in the All Patients Sections should be completed appropriately.
Understanding the MDEs

_How Does this Affect Patient Navigation Only Records_

Just as with the full MDE record, programs may choose to report breast and cervical data combined or separately in the Patient Navigation Only records. Because the Patient Navigation Only records do not have all of the MDE fields that are contained in the full record, it is necessary to provide separate guidance on how to complete breast and cervical data separately. For certain MDE variables the guidance is different between the full MDE record and the Patient Navigation only records. Please see the tables that follow for guidance on how to complete an MDE record when separating breast and cervical records. Please note that to properly identify a Patient Navigation Only record in the MDE file the Patient Navigation Paid field must be coded as (1) Yes and both the Cervical Service Paid by NBCCEDP Funds and the Breast Service Paid by NBCCEDP Funds fields must be coded as (2) No. All other scenarios will be considered a full MDE record and will be evaluated accordingly.

_How to Complete Cervical Data in the Patient Navigation Only MDE Record When Only Breast Data are Provided_

<table>
<thead>
<tr>
<th>ITEM NAME</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01 Patient Navigation Paid</td>
<td>(1) Yes</td>
</tr>
<tr>
<td>4.04 Cervical Service Paid by NBCCEDP Funds</td>
<td>(2) No</td>
</tr>
<tr>
<td>4.07 Result of Pap Test</td>
<td>Blank</td>
</tr>
<tr>
<td>4.08 Other Pap Test Result</td>
<td>Blank</td>
</tr>
<tr>
<td>4.09 Date of Pap test</td>
<td>Blank</td>
</tr>
<tr>
<td>4.11 HPV Test Result</td>
<td>Blank</td>
</tr>
<tr>
<td>4.12 Date of HPV Test</td>
<td>Blank</td>
</tr>
</tbody>
</table>

_How to Complete Breast Data in the Patient Navigation Only MDE Record When Only Pap and/or HPV Test Data are Provided_

<table>
<thead>
<tr>
<th>ITEM NAME</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01 Patient Navigation Paid</td>
<td>(1) Yes</td>
</tr>
<tr>
<td>5.02 Breast Service Paid by NBCCEDP Funds</td>
<td>(2) No</td>
</tr>
<tr>
<td>5.07 Initial Mammography Test Result</td>
<td>Blank</td>
</tr>
<tr>
<td>5.08 Date of Initial Mammogram</td>
<td>Blank</td>
</tr>
</tbody>
</table>
Data Quality Assessment

Feedback Reports

After the MDE file is submitted, feedback reports are generated, reviewed, and posted within 15 weeks of the submission due date. The purpose of the feedback reports is to assess the Program's data quality and to document the Program's performance in meeting goals established by the CDC. Below are descriptions of each type of feedback report. Sample copies of each of the feedback reports can be found on the www.nbccedp.org website.

Frequency Report

The frequency report contains counts and other related information pertaining to the MDE data file which was submitted. A count of the number of records with a screening date beyond the cut-off for the submission is displayed along with a frequency count for each variable in the MDE definition. Also, several variable cross-tabulations are generated.

This report is useful to conduct a gross review of data values and distributions for validity and compare these to previous submissions to ensure consistent reporting of historical data.

Edit Report

This report provides results from the MDE Edits Application, which validates an MDE file for valid data field values, logic checks across data fields, and consistency of data fields across records. The edit routine creates an edit summary report and an edit detail report. Since your Program has access to the MDE Edits Application and can generate these reports, only the edit summary report for the most recent 5 years of data is provided to you as a feedback report.

The edit summary report contains a count and associated percentage for records which trigger the edit. The messages and associated counts are divided into specific sections depending on the edit type.

The detail report contains detailed information on each record which triggered an edit. For each record which contains one or more edits, the Patient ID, Record ID, Pap test screening, mammogram screening and CBE screening dates are printed along with the edit. For each message, a list of all associated variable values pertaining to the message is printed.
Within the MDE Edits Application is the MDE Edits Documentation. This guide contains a detailed message description and recommended action for each edit generated. It is meant to help you to determine why the specific edit message was generated and an associated recommendation on how to correct the problem.

This report is useful to monitor data quality and clean MDE export data periodically and prior to data submission.

**Management Report**

The management report contains data from the final analytic file with duplicates removed. The various tables show different data distributions and in some cases, comparisons with aggregate data from all other Programs. The data are split into two separate time periods. The tables are explained by introductory paragraphs, along with several titles and footnotes.

This report is useful to gain a broad view of services provided, such as distribution of age by Pap tests performed or distribution of diagnostic workup based on screening result, to assess your program and compare to other programs to see if goals are met.

**Standard Audit Report**

The standard audit report is comprised of line listings by Patient ID, Record ID, and Enrollment Site for records that contain missing, unknown or conflicting data. An explanatory section can be found on page 2 of the standard audit report.

This report is useful to identify specific records that require investigation and resolution of critical clinical data to ensure adequate patient tracking and follow-up.

**Graphs (Plots)**

The Graphs contain a set of overall plots and a set of plots specific to your Program data. Please refer to the specific titles and footnotes for each graph that define the particular subset of data used to generate the graph.

This report is useful to visually present information on basic screening performance and program outcomes and to characterize the population served.
Data Quality Assessment

Data Quality Indicator Guide (DQIG)

The DQIG contains data from the final analytic file with duplicates removed. The tables compare demographic, Pap test and mammogram data using three separate time periods.

This report is useful for a comprehensive review of both data and service quality, and to compare these data over time to identify trends and issues to investigate.

Data Quality Indicator Guide Frequency Report

The DQIG Frequency Report is a companion report that contains various tables that outline the numerator and denominator for each of the items in the DQIG.

This report is useful when more complete data are needed to interpret DQIG performance measures.

Core Program Performance Indicators

The Core Program Performance Indicators is a succinct list of the DQIG items that the CDC considers most reflective of Program management. These items, along with other Program assessment tools, are used to help guide the CDC to assess technical assistance needs and to make performance based funding decisions. This report provides information on your Program data as well as the aggregate National Breast and Cervical Cancer Early Detection Program data.

This report is useful to compare program performance to CDC standards.

Histograms

The Histograms contain a graphic depiction of the National Breast and Cervical Cancer Early Detection Program data. The report focuses on the Core Performance Indicators. It provides a “de-identified” comparison of all comprehensive Programs to demonstrate where your Program lies in relation to other Programs. Please refer to the specific titles and footnotes for each graph that define the particular histogram.

This report is useful to compare program performance to other grantees.
Chapter 2

Minimum Data Elements (MDEs)

Version 7.0
**Abbreviated Records for Women Receiving ONLY Patient Navigation Services**

Grantees will report an abbreviated MDE record for women receiving navigation-only services who complete screening and/or diagnostics. The abbreviated record includes data on patient demographics, screening test type, date of test, test result, and final diagnosis. Access to medical record information will be needed to complete the MDE record. MDE data for navigated-only women will be analyzed separately and excluded in calculating the NBCCEDP Core Program Performance Indicators.

A Yes/No signifier (labelled PN ABBREVIATED FIELD) is provided for each Minimum Data Element below to indicate those fields that are included in the abbreviated, patient navigation-only MDE record.

*Note:* Grantees will continue to report a full MDE record on all women who receive NBCCEDP-funded breast and/or cervical screening/diagnostics along with NBCCEDP-funded patient navigation.
ITEM NO / NAME:  1.01:  State, Territorial or Tribal Program of Screening

PURPOSE:  To specify the Program Code for the state, territory or Tribal Program where screening occurred.

FIELD LOCATION:  1-2

LENGTH:  2

TYPE:  Numeric - right justify

PN ABBREVIATED FIELD:  YES

SKIP PATTERN:  This item should always be completed.

Patient Navigation-Only Records:  This item should always be completed.

CONTENTS:  Program Codes
01 = Alabama (AL)
02 = Alaska (AK)
04 = Arizona (AZ)
05 = Arkansas (AR)
06 = California (CA)
08 = Colorado (CO)
09 = Connecticut (CT)
10 = Delaware (DE)
11 = District of Columbia (DC)
12 = Florida (FL)
13 = Georgia (GA)
15 = Hawaii (HI)
16 = Idaho (ID)
17 = Illinois (IL)
18 = Indiana (IN)
19 = Iowa (IA)
20 = Kansas (KS)
21 = Kentucky (KY)
22 = Louisiana (LA)
23 = Maine (ME)
24 = Maryland (MD)
25 = Massachusetts (MA)
26 = Michigan (MI)
27 = Minnesota (MN)
28 = Mississippi (MS)
29 = Missouri (MO)
30 = Montana (MT)
31 = Nebraska (NE)
MDE Item Descriptions
Section 1: Program, Patient and Record Location
(All Patients Sections)

32 = Nevada (NV)
33 = New Hampshire (NH)
34 = New Jersey (NJ)
35 = New Mexico (NM)
36 = New York (NY)
37 = North Carolina (NC)
38 = North Dakota (ND)
39 = Ohio (OH)
40 = Oklahoma (OK)
41 = Oregon (OR)
42 = Pennsylvania (PA)
44 = Rhode Island (RI)
45 = South Carolina (SC)
46 = South Dakota (SD)
47 = Tennessee (TN)
48 = Texas (TX)
49 = Utah (UT)
50 = Vermont (VT)
51 = Virginia (VA)
53 = Washington (WA)
54 = West Virginia (WV)
55 = Wisconsin (WI)
56 = Wyoming (WY)

U.S. Territories Program Codes
60 = American Samoa (AS)
66 = Guam (GU)
68 = Republic of Marshall Islands (MH)
69 = Commonwealth of Northern Mariana Islands (MP)
70 = Republic of Palau (PW)
72 = Puerto Rico (PR)

Tribal Program Codes
73 = American Indian Cancer Foundation (AI)
75 = Great Plains (GP)
82 = Kaw Nation (KW)
83 = Yukon-Kuskokwim Health Corp. (YK)
85 = Southeast Alaska Regional Health Consortium (SE)
86 = Hopi Tribe (HT)
88 = Navajo Nation (NN)
89 = Native American Rehabilitation Association of the Northwest (NW)
90 = Arctic Slope (AC)
92 = Southcentral Foundation (SO)
96 = Cherokee Nation (CN)
97 = Cheyenne River Sioux (CR)
98 = South Puget Intertribal Planning Agency (SP)

EXPLANATION: Report the Program Code for your Program as specified in the Contents section.
REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Added Program Codes for Marshall Islands, American Indian Cancer Foundation, and Great Plains.</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 1.02: Unique Patient ID Number

PURPOSE: To specify patient's unique identification number.

FIELD LOCATION: 3-17

LENGTH: 15

TYPE: Alpha/numeric - left justify. No special symbols. Note that as an alpha/numeric field type, the character string must be reported consistently. For example, 00304 is NOT equivalent to 304 or 00000304.

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed.

**Patient Navigation-Only Records:** This item should always be completed.

EXPLANATION: Each patient must have a unique patient identification number that is consistent throughout your entire screening and tracking system. It will be used to track each woman over time within your Program. A patient identification number that is unique only to a specific clinic is not acceptable because a patient cannot be tracked between clinics. Completely numeric identifiers tend to work best; however, the MDEs allow the use of alpha-numeric identifiers if you find it necessary. Alphabetic characters must be entered consistently in uppercase or lowercase for all records for each patient.

Confidentiality is of the utmost importance. The CDC does not want to receive identification numbers that could be used to link the MDEs to other databases. Certain identification numbers, such as social security numbers, have this lack of privacy. If social security number or any other identification number that has the potential to be linked with other existing datasets is used, then the number must be encoded. The encoding procedure should not be provided to the CDC or IMS. It should be securely retained at your Program. In addition, your Program should ensure that the selected encoding procedure can be used to decode the Patient ID in the MDEs back to the original identification number in the event it is necessary.

Suggested encoding procedures can be digit rotation (simply rotating a set of digits) or “nines-complement” (nine minus the
number, i.e. the complement of 2 is 7). Please contact your IMS Technical Consultant for further guidance on developing a useable Patient ID encoding scheme.

REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number and field location. “Unique” added to item name. Guidance updated on using alphabetic characters (lowercase is permitted so long as the ID is entered consistently for all records for each patient).</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 1.03: Record Identifier

PURPOSE: To uniquely identify one record among many for a woman.

FIELD LOCATION: 18-25

LENGTH: 8

TYPE: Numeric - right justify

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed.

**Patient Navigation-Only Records:** This item should always be completed.

EXPLANATION: This item is used to uniquely identify one record among many for a woman. This could be a cycle number, a visit date, or a record number. In this context, record and screening cycle have the same meaning.

EXAMPLE: Using a date of 1/1/2011: 01012011
Using a cycle number of 1: 00000001
Cervical cycle number of 1: 10000001
Breast cycle number of 1: 20000001

REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number and field location.</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 2.01: County of Residence

PURPOSE: To specify the code for the county of residence.

FIELD LOCATION: 26-28

LENGTH: 3

TYPE: Numeric - right justify

PN ABBREVIATED FIELD: YES

SKIP PATTERN: Not required if Item 2.03 (ZIP Code of Residence) is completed.

Patient Navigation-Only Records: Not required if Item 2.03 (ZIP Code of Residence) is completed.

CONTENTS: A 3-digit numeric code or blank if unknown.

EXPLANATION: Specify the 3-digit code for the woman’s county of residence. A 3-digit code exists for each county in a state or territory. Contact your IMS Technical Consultant if you require guidance.

If your Program does not have counties, leave the item blank and complete Item 2.03 (ZIP Code of Residence).

For Tribal Programs, the woman's county of residence should be entered.

If the woman resides in another state, your Program should enter the correct 3-digit code for that county.

REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number and field location.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Updated skip pattern and explanation to reflect new item numbers.</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 2.02: State or Territory of Residence

PURPOSE: To specify the code for the state or territory of residence.

FIELD LOCATION: 29-30

LENGTH: 2

TYPE: Numeric - right justify

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed.

**Patient Navigation-Only Records:** This item should always be completed.

CONTENTS: A 2-digit code or blank if unknown.

EXPLANATION: Report the code for the state or territory as specified in Item 1.01.

For Tribal Programs, the woman's state of residence should be entered.

This item was added because many Programs screen women from out of state and some Tribal Programs screen women from several states.

REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
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</thead>
<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number and field location.</td>
</tr>
</tbody>
</table>

MDE 7.0 Data User’s Manual
Revised August 2019
ITEM NO / NAME: 2.03: ZIP Code of Residence

PURPOSE: To specify ZIP code of residence.

FIELD LOCATION: 31-35

LENGTH: 5

TYPE: Numeric - right justify

PN ABBREVIATED FIELD: YES

SKIP PATTERN: Not required if Item 2.01 (County of Residence) is completed.

**Patient Navigation-Only Records:** Not required if Item 2.01 (County of Residence) is completed.

CONTENTS: A 5-digit numeric code or blank if unknown.

REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
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</thead>
<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number and field location.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Updated skip pattern to reflect new item numbers.</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 2.04: Date of Birth

PURPOSE: To specify the woman’s date of birth.

FIELD LOCATION: 36-41

LENGTH: 6

TYPE: Date - MMYYYY format

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed.

Patient Navigation-Only Records: This item should always be completed.

CONTENTS: A 6-digit numeric item of the form MMYYYY, where MM (month) is a number from 1 to 12 and YYYY is the year of birth. If just the year is known, then blank fill the month. At a minimum, the year of birth must be reported.

EXPLANATION: This item is used to compute age values and is vital for analyses. It is, therefore, important to provide as complete a date of birth as possible.

REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
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<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number, field location, and length.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Updated format and contents to reflect removal of day of birth from this item.</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 2.05: Hispanic or Latino Origin

PURPOSE: To specify if the woman self-reported as Hispanic or Latino origin.

FIELD LOCATION: 42

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed.

**Patient Navigation-Only Records:** This item should always be completed.

CONTENTS: 1 = Yes
2 = No
3 = Unknown

Unknown in this context can mean: (a) the woman was not asked, (b) the answer was not recorded, (c) the woman did not know, or (d) the woman refused to answer.

EXPLANATION: The preferred method of identifying Hispanic or Latino Origin is self-identification by the woman. Consider placing this item prior to race on the data form for better completion of the race/ethnicity data.

If Hispanic or Latino Origin is not collected separately from race on your forms and a woman reports her race as ‘Hispanic’, Hispanic or Latino origin would be reported as 1 (Yes) and race would be reported as 7 (Unknown). If a woman reports her race as something other than ‘Hispanic’ or ‘Latino’, Hispanic or Latino Origin would be reported as 3 (Unknown).

Programs that do not collect Hispanic/Latino Origin and Race separately, should consider using options such as ‘White, Hispanic’, ‘White, non-Hispanic’, etc. to help improve reporting of race/ethnicity data.
REVISION HISTORY:

<table>
<thead>
<tr>
<th>MDE version</th>
<th>Date of revision</th>
<th>Type of revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number and field location.</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 2.06.1: Race 1

PURPOSE: To specify the woman’s self-reported race.

FIELD LOCATION: 43

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed.

**Patient Navigation-Only Records:** This item should always be completed.

CONTENTS: 1 = White  
2 = Black or African American  
3 = Asian  
4 = Native Hawaiian or Other Pacific Islander  
5 = American Indian or Alaska Native  
7 = Unknown  
8 = Asian/Pacific Islander (version 4.1 only)

EXPLANATION: If a woman reports more than one race category, Items 2.06.2 through 2.06.5 should be used to report the additional race categories.

If 2.05 (Hispanic or Latino Origin) is not collected separately from race, and the woman indicates her race to be ‘Hispanic’, then race would be reported to the CDC as 7 (Unknown) and 2.05 (Hispanic or Latino Origin) would be reported as 1 (Yes).

All race data collected prior to 10/01/2002 should be reported in the Race 1 item. If a woman subsequently reports her race as multi-racial, data should be updated using Race 1-5, as necessary.

Due to revised standards for the classification of federal data on race and ethnicity, the following changes are in effect:

a) The previous race category of “Asian/Pacific Islander” is separated into two race categories. For data collected prior to 10/01/2002, where race was reported using the combined category of Asian/Pacific Islander, it is not necessary to
convert this category into the new separate values. These older cases should be placed in the Race 1 item (2.06.1) using 8 (Asian/Pacific Islander). Beginning 10/01/2002, the race category of “Asian/Pacific Islander” should not be placed on data collection forms for selection by new patients or on data entry screens as an option for new data entry.

b) The race category of ‘Other’ was removed as a reporting option, beginning 10/01/2002. For data collected prior to 10/01/2002, where race was reported as 6 (Other), this value should be converted to the category of 7 (Unknown). It is strongly recommended that the category of ‘Other’ should be removed from data collection forms.

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</table>
ITEM NO / NAME: 2.06.2: Race 2

PURPOSE: To specify a second race for women who self-identify themselves as multi-racial.

FIELD LOCATION: 44

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should be completed if the woman identifies herself as more than one race. Otherwise leave blank.

Patient Navigation-Only Records: This item should be completed if the woman identifies herself as more than one race. Otherwise leave blank.

CONTENTS: 1 = White
2 = Black or African American
3 = Asian
4 = Native Hawaiian or Other Pacific Islander
5 = American Indian or Alaska Native
7 = Unknown

EXPLANATION: This item should be left blank unless the woman reports more than one race. If a woman reports more than one race category, Items 2.06.2 through 2.06.5 should be used to report the additional race categories.

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</table>
ITEM NO / NAME: 2.06.3: Race 3

PURPOSE: To specify a third race for women who self-identify themselves as multi-racial.

FIELD LOCATION: 45

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should be completed if the woman identifies herself as more than two races. Otherwise leave blank.

Patient Navigation-Only Records: This item should be completed if the woman identifies herself as more than two races. Otherwise leave blank.

CONTENTS: 1 = White
2 = Black or African American
3 = Asian
4 = Native Hawaiian or Other Pacific Islander
5 = American Indian or Alaska Native
7 = Unknown

EXPLANATION: This item should be left blank unless the woman reports more than two races. The preferred method of identifying race is self-identification by the woman. If a woman reports more than one race category, items 2.06.2 through 2.06.5 should be used to report the additional race categories.

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</table>
ITEM NO / NAME: 2.06.4: Race 4

PURPOSE: To specify a fourth race for women who self-identify themselves as multi-racial.

FIELD LOCATION: 46

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should be completed if the woman identifies herself as more than three races. Otherwise leave blank.

**Patient Navigation-Only Records:** This item should be completed if the woman identifies herself as more than three races. Otherwise leave blank.

CONTENTS: 1 = White  
2 = Black or African American  
3 = Asian  
4 = Native Hawaiian or Other Pacific Islander  
5 = American Indian or Alaska Native  
7 = Unknown

EXPLANATION: This item should be left blank unless the woman reports more than three races. The preferred method of identifying race is self-identification by the woman. If a woman reports more than one race category, items 2.06.2 through 2.06.5 should be used to report the additional race categories.

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ITEM NO / NAME:  2.06.5:  Race 5

PURPOSE:  To specify a fifth race for women who self-identify themselves as multi-racial.

FIELD LOCATION:  47

LENGTH:  1

TYPE:  Numeric

PN ABBREVIATED FIELD:  YES

SKIP PATTERN:  This item should be completed if the woman identifies herself as more than four races. Otherwise leave blank.

Patient Navigation-Only Records: This item should be completed if the woman identifies herself as more than four races. Otherwise leave blank.

CONTENTS:  1 = White
          2 = Black or African American
          3 = Asian
          4 = Native Hawaiian or Other Pacific Islander
          5 = American Indian or Alaska Native
          7 = Unknown

EXPLANATION:  This item should be left blank unless the woman reports more than four races. The preferred method of identifying race is self-identification by the woman. If a woman reports more than one race category, items 2.06.2 through 2.06.5 should be used to report the additional race categories.

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</table>
ITEM NO / NAME: 3.01: Patient Navigation Paid by NBCCEDP Funds

PURPOSE: To determine if patient navigation was paid for with NBCCEDP funds.

FIELD LOCATION: 48

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed for screening cycles beginning January 1, 2019. Historical data should be coded as 3 (Unknown).

**Patient Navigation-Only Records:** This item should always be completed.

CONTENTS: 1 = Yes
2 = No
3 = Unknown

EXPLANATION: If patient navigation is delivered (consistent with CDC policy) using CDC funds to support the navigation (e.g. reimbursement fee-for-service, paid for staff delivering PN), select 1 (Yes.)

A response of 2 (No) should be selected if CDC funds were not used for patient navigation or if patient navigation was not delivered.

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ITEM NO / NAME: 4.01: Previous Pap Test

PURPOSE: To determine if a woman has had a previous Pap test.

FIELD LOCATION: 49

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: This item should always be completed.

CONTENTS: 1 = Yes
2 = No
3 = Unknown

Unknown in this context can mean: (a) the woman was not asked, (b) the answer was not recorded, (c) the woman did not know, or (d) the woman refused to answer.

If a Pap test is not performed (i.e., breast exam record only) then a response of 3 (Unknown) should be reported. For further guidance on reporting breast and cervical records separately, please see Chapter 1 “Understanding MDE Data”.

For the first Pap test record for a woman, this item should be answered ‘Yes’, ‘No’ or ‘Unknown’. For subsequent cervical records, Previous Pap Test should be completed as ‘Yes’.

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</table>
ITEM NO / NAME: **4.02: Date of Previous Pap Test**

PURPOSE: To specify the date of the previous Pap test.

FIELD LOCATION: 50-55

LENGTH: 6

TYPE: Date - MMYYYY format

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If 4.01 (Previous Pap Test) is 1 (Yes), this item should be completed if known; otherwise it should be blank.

CONTENTS: A 6-digit numeric item of the form MMYYYY, where MM (month) is a number from 1 to 12 and YYYY is the year of the Previous Pap Test. If the year of Previous Pap Test is known, but the month is not, blank fill just the month (e.g. _ _2008). An invalid date such as 99/9999 will be treated as a missing date for the MDE feedback reports.

For the first Pap test record for a woman, a date should be provided if 4.01 (Previous Pap Test) is 1 (Yes); otherwise it should be left blank. For a woman’s subsequent records, Programs may choose to report either the date of the previous Pap test that was reported in cycle 1, or the date of the Pap test that was performed in the preceding cycle.

**e.g.**, Cycle 1

- 4.01 (Previous Pap test) = 1 (Yes)
- 4.02 (Previous Pap date) = 02/2007
- 4.09 (Pap test Date) = 01/01/2008.

Cycle 2

- 4.01 (Previous Pap Test) = 1 (Yes)
- 4.02 (Date of Previous Pap) may be 02/2007 or 01/2008.

Once a decision is made on which date to use, Programs must use it consistently for each woman and for each record.
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</tbody>
</table>
ITEM NO / NAME: 4.03: Indication for Pap Test

PURPOSE: To report the indication/purpose of the cervical cycle.

FIELD LOCATION: 56

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: This item should always be reported for cervical cycles beginning January 1, 2009. The indication for historical Pap Test Result values can be reported if accurately collected; otherwise, this item should be reported as 9 (Unknown).

If no cervical services were provided or reported in this record, report 5 (no cervical service).

CONTENTS: 1 = Screening  
2 = Surveillance  
3 = Non-program Pap test, referred in for diagnostic evaluation  
4 = No Pap  
5 = No cervical service  
6 = Pap after primary HPV+  
9 = Unknown

EXPLANATION: If Indication for Pap Test is ‘5’ then items 4.04 – 4.13 should be blank.

Data collection for this field is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise, code as 9 (Unknown).

A response of 1 (Screening) should be reported for a Pap test performed as part of a routine screening schedule. Items 4.04 – 4.13 should be reported as appropriate. Item 4.06 should be blank.

A response of 2 (Surveillance) should be reported for a Pap test performed on a woman under management for a cervical abnormality (abnormal Pap or HPV) detected prior to this cycle. Items 4.04 – 4.13 should be reported as appropriate. Item 4.06 should be blank.
A response of 3 (Non-program Pap test, referred in for diagnostic evaluation) should be reported when a patient has had a Pap test performed outside of the Program, and is referred to the Program for diagnostic work-up. Referral Date (4.06) must be completed, and a valid Pap test Result should be provided: (4.07) ‘1’-‘11’ or ‘14’.

A response of 4 (No Pap) should be reported when the patient does not have a screening Pap test and goes directly to Diagnostic Work-up or only had a primary HPV test. Items 4.06 – 4.09 should be blank.

A response of 5 (No Cervical Service) should be reported when no cervical services are provided or reported in this record, only breast services. Items 4.04 – 4.13 should be blank.

A response of 6 (Pap after primary HPV+) should be reported when a Pap test is done as follow-up to a positive (other 12) primary HPV test. Items 4.04 – 4.13 should be reported as appropriate. Item 4.06 should be blank.

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<td>08/01/2019</td>
<td>Updated item number and field location. Updated contents to reflect new responses. Updated explanation to reflect new guidance and item numbers. Added 6 (Pap after primary HPV+).</td>
</tr>
</tbody>
</table>
ITEM NO / NAME: 4.04: Cervical Service Paid by NBCCEDP Funds

PURPOSE: To determine if one or more cervical services were paid using NBCCEDP Funds.

FIELD LOCATION: 57

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If 4.03 (Pap Indication) is 5, then this item must be blank.

**Patient Navigation-Only Records:** This item should always be completed with a response of 2 (No.)

CONTENTS: 1 = Yes
2 = No
3 = Unknown

EXPLANATION: Data collection for this field is effective 01/01/2019. Historical data can be reported if accurately collected; otherwise, code as ‘3’ (Unknown).

A response of 1 (Yes) should only be used if any screening or diagnostic cervical services were paid with NBCCEDP funds.

A response of 2 (No) should be used when no screening or diagnostic cervical services were paid with NBCCEDP funds.

‘Unknown’ in this context means that it is unclear at the time of the MDE submission which funds will be used to pay for cervical services, or that it was not clearly indicated what funds were used. This item may be updated to ‘Yes’ or ‘No’ once the data are retrieved.

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<td>New field added.</td>
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</table>
ITEM NO / NAME: 4.05: High Risk for Cervical Cancer

PURPOSE: To determine risk for developing cervical cancer.

FIELD LOCATION: 58

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If 4.03 (Pap Indication) is 5, then this item must be blank.

CONTENTS: 1 = Yes
2 = No
9 = Not assessed/Unknown

EXPLANATION: Data collection for this field is effective 01/01/2019. Historical data should be coded as ‘9’ (Unknown).

A response of 1 (Yes) should be reported if risk was assessed and determined to be high risk, as defined as prior DES exposure and/or immunocompromised patients.

A response of 2 (No) should be reported if risk was assessed and not determined to be high risk.

A response of 9 (Not assessed/Unknown) should be reported if risk was not assessed, family history was not taken, genetic testing was not done or if risk is unknown.

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</table>
ITEM NO / NAME: **4.06: Cervical Diagnostic Referral Date**

PURPOSE: To specify the enrollment date for a woman referred in to the Program for diagnostic evaluation.

FIELD LOCATION: 59-66

LENGTH: 8

TYPE: Numeric – right justify

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If 4.03 (Indication for Pap test) = 3 (Referred for diagnostics), then this item should be completed; otherwise, this item should be left blank.

Data collection for this item is effective January 1, 2009. Historical data can be reported if accurately collected; otherwise this item should be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of the Cervical Diagnostic Referral Date. If just the year is known, then blank fill the month and day. If just the year and month are known, blank fill the day (e.g. 01_ _2011).

EXAMPLE: A woman is referred to the Program on May 5, 2011 for a colposcopy: 05052011.

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</table>
ITEM NO / NAME: 4.07: Result of Pap Test

PURPOSE: To report the result of the Pap test using simplified categories from all Bethesda Reporting Systems

FIELD LOCATION: 67-68

LENGTH: 2

TYPE: Numeric - right justify

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If Item 4.03 (Pap Indication) is 4 or 5, then this item must be left blank.

Patient Navigation-Only Records: If a Pap test was done or is pending, then this item must be completed.

CONTENTS: 1 = Negative for intraepithelial lesion or malignancy
2 = Infection/Inflammation/Reactive Changes (Bethesda 1991)
3 = Atypical squamous cells of undetermined significance (ASC-US)
4 = Low grade SIL (including HPV changes)
5 = Atypical squamous cells cannot exclude HSIL (ASC-H Bethesda 2001)
6 = High grade SIL
7 = Squamous Cell Carcinoma
8 = Atypical Glandular Cells (Bethesda 2014)
9 = Adenocarcinoma in situ (AIS) (Bethesda 2014)
10 = Adenocarcinoma (Bethesda 2014)
11 = Other
12 = Unsatisfactory
13 = Result Pending
14 = Results unknown, presumed abnormal, Pap test from non-program funded source

If the result of the Pap test is a 5, 6, 7, 8, 9, 10 or 14, the Cervical Diagnosis Information Section MUST be completed. If the result is a 1, 2, 3, or 4 and the clinician chooses to perform a diagnostic work-up, the Cervical Diagnosis Information Section MUST also be completed. In either of these cases Item 4.13 (Diagnostic work-up planned for cervical dysplasia or cancer) should be set to 1 (Yes).

EXPLANATION: These categories correspond to the Bethesda 1991, Bethesda 2001, and Bethesda 2014 Systems for reporting cervical cytological
diagnoses. Refer to the Pap Test Conversion Table in Appendix 6 for guidance on how the results of each Bethesda System align with this item.

A response of 1 (Negative) is used to indicate that there is no cellular evidence of neoplasia, whether or not there are any organisms or other non-neoplastic findings such as reactive changes, inflammation or atrophy.

A response of 11 (Other) should be used if the cytology report indicates a result that is not a valid Bethesda result. Please provide the result in Item 4.08 (Other Pap Test Result). Be careful regarding what is coded in ‘Other’, as these results are difficult to use for analysis.

Pelvic exam findings should not be reported as Other Pap test results. It is not necessary to indicate pelvic exam findings in order to validate the need for diagnostic work-up. It is important to collect this information for Program purposes, but pelvic exam findings should not be reported in the MDEs.

Post-hysterectomy vaginal smears are appropriate to perform, and to report as a Pap test in the MDEs, as long as the hysterectomy was performed due to a cervical cancer or CIN. Results for these types of smears should use the same Bethesda categories as Pap tests. Vaginal smears should NOT have a result of VIN or VAIN, as these results can only be obtained through a biopsy diagnosis.

Similarly, findings of CIN1, CIN2 or CIN3 should not be reported as Other Pap test Results. These results are only obtained through a biopsy diagnosis and would be reported as the Cervical Final Diagnosis (6.02).

In addition, findings such as atrophy, lesions, epithelial cell abnormalities and other malignant neoplasia, and procedures such as hormonal evaluation, should not be reported as Other Pap test Results.

A response of 12 (Unsatisfactory) should be used when there are insufficient cervical cells present for a reasonable evaluation of the material. A repeat Pap test should be performed as soon as it is clinically possible, and a new MDE record initiated. Programs should monitor the number of unsatisfactory Pap test results for possible provider or cytology lab concerns.
A response of 13 (Pending) means that either the test result is pending or that the test is scheduled to be performed. It is not recommended that this option be placed on data collection forms.

A response of 14 (Presumed abnormal) should be reported when a patient receives a Pap test outside of the Program but the actual Pap test result cannot be obtained. The result is presumed to be abnormal; otherwise, the woman would not have been referred to the Program for diagnostic work-up. If the actual result from the outside Pap test is known, then it should be reported. Item 4.03 (Indication for Pap test) should be reported as 3 (Non-program Pap, Referred in for diagnostic evaluation).

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<td>New Field Added</td>
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</table>
ITEM NO / NAME: 4.08: Other Pap Test Result

PURPOSE: To specify an “other” Pap test result.

FIELD LOCATION: 69-88

LENGTH: 20

TYPE: Character - left justify

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If Item 4.03 (Pap Indication) is 4 or 5, then this item must be left blank.

If Item 4.07 (Result of Pap test) is 11 (Other), this item should be completed; otherwise it should be blank.

**Patient Navigation-Only Records:** If Item 4.07 (Result of Pap test) is 11 (Other), then this item must be completed; otherwise it should be blank.

CONTENTS: This is a free text item.

EXPLANATION: The purpose of this item is to include results that do not fit into the other Bethesda result categories. Please try to use this item appropriately. Reclaiming inappropriate "other" responses is time-consuming and could potentially result in the loss of valuable data.

Acceptable categories to report as Other include “Endometrial Cells” and “Specimen lost before evaluation”.

Pelvic exam findings should not be reported as Other Pap test results. It is not necessary to indicate pelvic exam findings in order to validate the need for diagnostic work-up. It is important to collect this information for Program purposes, but pelvic exam findings should **not** be reported in the MDEs.

Post-hysterectomy vaginal smears are appropriate to perform, and to report as a Pap test (4.07) in the MDEs, as long as the hysterectomy was performed due to a cervical cancer or CIN. Results for these types of smears should use the same Bethesda categories as Pap tests. Vaginal smears should **NOT** have a result of VIN or VAIN, as these results can only be obtained through a biopsy diagnosis.
Similarly, findings of CIN1, CIN2 or CIN3 should not be reported in the Other Pap test Results item. These results are only obtained through a biopsy diagnosis and would be reported as a Cervical Final Diagnosis (6.02). Programs should refrain from including follow-up recommendations or reasons why the Pap test was not performed in the Other Pap test Results item. This item should be limited to reporting the result of a Pap test that was performed, and whose result does not fit into one of the appropriate Bethesda result categories.

Below is a list of potential categories and how to code them.

<table>
<thead>
<tr>
<th>Other Specify Text</th>
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<tbody>
<tr>
<td>Atrophic Atypia</td>
<td>(3) ASCUS</td>
</tr>
<tr>
<td>Atypia</td>
<td>(3) ASCUS</td>
</tr>
<tr>
<td>Bacteria</td>
<td>(2) Infection/Inflammation</td>
</tr>
<tr>
<td>Cervicitis</td>
<td>(2) Infection/Inflammation</td>
</tr>
<tr>
<td>HPV Changes</td>
<td>(4) LSIL</td>
</tr>
<tr>
<td>Hyperkeratosis</td>
<td>(2) Infection Inflammation</td>
</tr>
<tr>
<td>Mild Dysplasia</td>
<td>(4) LSIL</td>
</tr>
<tr>
<td>Moderate Dysplasia</td>
<td>(6) HSIL</td>
</tr>
<tr>
<td>Negative Vaginal Smear</td>
<td>(1) Negative</td>
</tr>
<tr>
<td>Severe Dysplasia</td>
<td>(6) HSIL</td>
</tr>
<tr>
<td>Squamous Metaplasia / Metaplastic cells</td>
<td>(1) Negative</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>(2) Infection/Inflammation</td>
</tr>
<tr>
<td>Vaginosis / Vaginitis</td>
<td>(2) Infection/Inflammation</td>
</tr>
<tr>
<td>Unsatisfactory</td>
<td>(12) Unsatisfactory</td>
</tr>
</tbody>
</table>

Below is a list of items that should not be reported as Other Pap test Results:

- No endocervical cells or component
- Lack of endocervical cells
- Epithelial cell abnormalities
- Transfer zone absent
- CIN1, CIN2, CIN3, or other malignant Neoplasia
- CIS
- Atrophy
- Lesions
- VAIN; VIN
- Pelvic exams
- Hormonal evaluation
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</table>
ITEM NO / NAME: 4.09: Date of Pap Test

PURPOSE: To specify the date that the Pap test was performed.

FIELD LOCATION: 89-96

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If 4.03 (Pap Indication) is 4 or 5, then this item must be blank. If Item 4.07 (Result of Pap test) is coded as 1 - 12, this item should be completed. If Item 4.07 is 13 (Pending) or 14 (Result unknown, presumed abnormal), and the date is known, this item should be completed; otherwise it should be left blank.

Patient Navigation-Only Records: If Item 4.07 (Result of Pap test) is coded as 1-12, then this item should be completed. If Item 4.07 is 13 (Pending) or 14 (Result unknown, presumed abnormal), and the date is known, this item should be completed; otherwise it should be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of the screening Pap test. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

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</table>
ITEM NO / NAME: 4.10: Indication for HPV Test

PURPOSE: To report the indication/purpose of the HPV test.

FIELD LOCATION: 97

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 4.03 (Pap Indication) is 5, then this item must be blank.

Data collection for this item is effective 01/01/2019. For cycles before 01/01/2019 where an HPV test was not performed, code as 3 (Test Not Done). Other historical data were an HPV test was done can be reported if accurately collected; otherwise code as 9 (Unknown).

CONTENTS: 1 = Co-Test/Screening
2 = Reflex
3 = Test Not Done
9 = Unknown

EXPLANATION: A response of 1 (Co-Test/Screening) should be reported if HPV test is performed alone or in combination with a Pap test as part of cervical cancer screening. A response of 2 (Reflex) should be reported if a HPV test is performed as a follow-up test after a screening Pap test.

A response of 3 (Test not done) should be reported if the HPV test was not performed.

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ITEM NO / NAME: 4.11: HPV Test Result

PURPOSE: To report the result of a high risk HPV test.

FIELD LOCATION: 98

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If Item 4.03 (Pap Indication) is 5, then this item must be blank.

If Item 4.10 (HPV Indication) is 3, then this item must be blank.

Data collection for this item is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise this item should be left blank.

Patient Navigation-Only Records: If an HPV test was done, then this item must be completed.

CONTENTS: 1 = Positive with genotyping not done/unknown
2 = Negative
4 = Positive with positive genotyping
5 = Positive with negative genotyping
9 = Unknown

EXPLANATION: This item should be used to report HPV tests performed for screening or surveillance. The NBCCEDP follows the ASCCP Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests.

A response of 1 (Positive with genotyping not done/unknown) should be reported if the HPV test was positive and genotyping was unknown or genotyping was not done.

A response of 4 (Positive with positive genotyping) should be reported if the HPV test was positive and genotyping identifies type 16 or 18.

A response of 5 (Positive with negative genotyping) should be reported if the HPV test was positive and genotyping does not identify type 16 or 18.
If an HPV test was performed, but the result is not known at the time of the MDE submission, please code as 9 (Unknown) and update with the actual test result once it is known.

HPV tests that are provided in a manner that is consistent with the current NBCCEDP reimbursement policy for HPV DNA testing should be reported in the MDEs, regardless of payment source.

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<td>Removed 3 (Test Not Done).</td>
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<td>Added 4 (Positive with positive genotyping)</td>
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<td>Added 4 (Positive with negative genotyping)</td>
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ITEM NO / NAME: **4.12: Date of HPV Test**

PURPOSE: To report the date of the HPV sample collection.

FIELD LOCATION: 99-106

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If Item 4.03 (Pap Indication) is 5, then this item must be left blank.

If Item 4.10 (HPV Indication) is 3, then this item must be left blank.

Data collection for this item is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise this item should be left blank.

If Item 4.11 (HPV Test Result) is 1, 2, 4, 5, or 9, then this item must be completed.

**Patient Navigation-Only Records:** If Item 4.11 (HPV Test Result) is 1, 2, 4, 5, or 9, then this item must be completed.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of the screening Pap test. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

This should be the date of sample collection, not the date that the HPV test result was received.

EXAMPLE: A woman has a Pap test on 2/13/2011. Cytology specimens were reserved for possible HPV testing. An HPV test was performed on 3/05/2011 to test for high risk HPV strains. Date of HPV: 02132011.
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ITEM NO / NAME: 4.13: Diagnostic Work-up Planned for Cervical Dysplasia or Cancer

PURPOSE: To indicate the clinical recommendation for immediate diagnostic work-up.

FIELD LOCATION: 107

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If 4.03 (Indication for Pap test) is 1, 2, 3, 4, 6 or 9, then this item must be completed; otherwise, this item should be left blank.

If 4.03 (Indication for Pap test) is 3 (Non-program Pap, Referred in for diagnostic evaluation), then Item 4.13 must be 1 (Diagnostic work-up planned on basis of abnormal Pap test or pelvic exam) and the Cervical Final Diagnosis Information Section must be completed.

CONTENTS: 1 = Diagnostic work-up planned on basis of abnormal Pap test, HPV test or pelvic exam.
2 = Diagnostic work-up not planned.
3 = Diagnostic work-up plan not yet determined.

EXPLANATION: This item was created to eliminate confusion about which women are to have immediate diagnostic work-up. This item should reflect the clinical recommendation for diagnostic work-up.

If Item 4.07 (Result of Pap Test) is 5, 6, 7, 8, 9, 10 or 14, then Item 4.13 should be 1 (Diagnostic work-up planned) and the Cervical Final Diagnosis Information Section must be completed.

If this item is coded as 1 (Planned), then the Cervical Final Diagnosis Information Section must be completed. If this item is coded as 2 (Not Planned) or 3 (Not Yet Determined), then the Cervical Final Diagnosis Information Section must be left blank.

A response of 1 (Planned) indicates that based on the pelvic exam, the Pap test result, the HPV test result and/or the woman’s concerns, immediate diagnostic testing has been planned in order to rule out cancer.
A response of 2 (Not Planned) indicates that based on the pelvic exam, the Pap test result, the HPV test result and/or the woman’s concerns, no immediate diagnostic testing is planned.

If Item 4.07 (Result of Pap Test) is 5, 6, 7, 8, 9, 10 or 14 and case management review confirmed that the provider chose to have the woman return for a short-term follow-up exam (3 months, 6 months, etc.) instead of the clinical recommendation for immediate diagnostic work-up (e.g. colposcopy), then indicate diagnostic work-up planned as 1 (Workup Planned) and Item 6.01 (Status of Final Diagnosis) should be reported as 9 (Irreconcilable). The short-term follow-up visit should begin a new cycle.

Reflex HPV testing following an abnormal Pap test is not considered diagnostic work-up in the MDEs. If the clinical recommendation following a Pap test and HPV test is to perform immediate diagnostic work-up, then report Item 4.13 as 1 (Planned). Otherwise, report Item 4.13 as 2 (Not Planned).

A response of 3 (Not Yet Determined) should be used when the screening results are either pending, or the physician has not yet indicated whether work-up is planned. This code is to be used for administrative purposes and does not need to be added to your forms. This code can be used to create a suspense file for tracking outstanding screening results.

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<td>Updated guidance for which Pap Test results require workup.</td>
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</table>
ITEM NO / NAME: 5.01: Indication for Initial Mammogram

PURPOSE: To report the indication/purpose of the mammogram.

FIELD LOCATION: 108

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: This item should always be reported for breast cycles beginning January 1, 2009. The indication for historical Initial Mammogram Result values can be reported if accurately collected; otherwise, this item should be reported as 9 (Unknown).

If no breast services were provided or reported in this record, report 5 (No Breast Service).

CONTENTS: 1 = Screening
2 = Diagnostic
3 = Non-program mammogram, Referred in for diagnostic evaluation
4 = No mammogram
5 = No Breast Service
9 = Unknown

EXPLANATION: Report “1” if the initial mammogram was performed as part of a routine or annual screening schedule and in the absence of symptoms or a recent positive CBE. Items 5.02 through 5.11 should be completed as appropriate, except Item 5.03, which should be blank.

Report “2” if the initial mammogram was performed as additional evaluation of a recent mammogram prior to this cycle, evaluation of current symptoms or abnormal CBE finding or prior history of breast cancer. Items 5.02 through 5.11 should be completed as appropriate, except Item 5.03, which should be blank.

Report “3” if the initial mammogram was performed outside of the Program and the woman was referred into the Program for diagnostic evaluation. Item 5.03 (Breast Diagnostic Referral Date) must be completed, and a valid Mammogram Result (5.07) of 1-5, 7, 11, or 14-15 must be entered.
Report “4” if the woman did not receive an initial mammogram but did receive at least one breast procedure including:

- a CBE either within or outside of the Program.
- a screening MRI either within or outside of the Program.
- a breast imaging procedure (other than an initial mammogram) within the Program or diagnostic work-up within the Program.

When using this code, Items 5.07 and 5.08 should be left blank.

Report “5” if no breast services are provided or reported in the record, only cervical services. Items 5.02 through 5.11 should be left blank.

A response of 9 (Unknown), in this context means that (a) the provider or clinical record did not indicate the intent/purpose of this initial mammogram, or (b) it was not asked.

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</table>
ITEM NO / NAME: 5.02: Breast Service Paid by NBCCEDP Funds

PURPOSE: To indicate if one or more breast services were paid using NBCCEDP funds.

FIELD LOCATION: 109

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If 5.01 (Mammogram Indication) is 5, then this item must be blank.

**Patient Navigation-Only Records:** This item should always be completed with a response of 2 (No.)

CONTENTS: 1 = Yes  
2 = No  
3 = Unknown

EXPLANATION: Data collection for this field is effective 01/01/2019. Historical data can be reported if accurately collected; otherwise, code as ‘3’ (Unknown).

A response of 1 (Yes) should only be used if the mammogram, CBE, or at least one breast imaging or diagnostic procedures was paid by NBCCEDP funds.

A response of 2 (No) should be used when reporting non-program funded breast procedures.

‘Unknown’ in this context means that it is unclear at the time of the MDE submission which funds will be used to pay for breast services, or that it was not clearly indicated what funds were used. This item may be updated to ‘Yes’ or ‘No’ once the data are retrieved.

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ITEM NO / NAME:  5.03:  Breast Diagnostic Referral Date

PURPOSE:  To specify the enrollment date for a woman referred in to the Program for diagnostic evaluation.

FIELD LOCATION:  110-117

LENGTH:  8

TYPE:  Date – MMDDYYYY format

PN ABBREVIATED FIELD:  NO

SKIP PATTERN:  If Item 5.01 (Indication for Initial Mammogram) = 3 (Referred in for diagnostic evaluation) then this item should be completed.

If Item 5.01 (Indication for Initial Mammogram) = 4 (No mammogram), then this item should only be completed if no initial mammogram was performed and the woman was referred into the Program based upon an abnormal CBE performed outside of the Program; otherwise, this item should be left blank.

Data collection for this item is effective January 1, 2009. Historical data can be reported if accurately collected; otherwise, this item should be left blank.

CONTENTS:  An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of the Breast Diagnostic Referral Date. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

EXAMPLE:  A woman is referred to the Program on May 5, 2011 for an Ultrasound following an abnormal screen provided outside of the program: 05052011.

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ITEM NO / NAME: 5.04: High Risk for Breast Cancer

PURPOSE: To determine risk for developing breast cancer.

FIELD LOCATION: 118-118

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If 5.01 (Mammogram Indication) is 5, then this item must be blank.

CONTENTS: 1 = Yes
2 = No
9 = Not assessed/Unknown

EXPLANATION: Data collection for this field is effective 01/01/2019. Historical data should be reported as ‘9’ (Unknown).

A response of 1 (Yes) should be reported if risk was assessed and determined to be high risk as defined as a woman with BRCA mutation, a first-degree relative who is a BRCA carrier, a lifetime risk of 20-25% or greater as defined by risk assessment models, radiation treatment to the chest between ages 10-30, or personal or family history of genetic syndromes like Li-Fraumeni syndrome.

A response of 2 (No) should be reported if risk was assessed and not determined to be high risk

A response of 9 (Not assessed/Unknown) should be reported if risk was not assessed, family history was not taken, genetic testing was not done or if risk is unknown.

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<td>New field added.</td>
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ITEM NO / NAME: 5.05: Screening MRI Results

PURPOSE: To report the result of the screening MRI.

FIELD LOCATION: 119-119

LENGTH: 1

TYPE: Numeric - right justify

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If 5.01 (Mammogram Indication) is 5, then this item must be blank.
If 5.04 (High Risk for Breast Cancer) is 2 or 9, then this item must be blank.

CONTENTS: 1 = Negative (Category 1)
2 = Benign finding (Category 2)
3 = Probably benign indicated (Category 3)
4 = Suspicious (Category 4)
5 = Highly suggestive of malignancy (Category 5)
6 = Known malignancy (Category 6)
7 = Incomplete – need additional imaging evaluation (Category 0)
8 = Results pending
9 = Not done

If result is 4, 5, or 7, the Breast Final Diagnosis Section must be completed and Item 5.11 (Additional Procedures Needed to Complete Breast Cycle) must be 1 (Yes).

EXPLANATION: Data collection for this field is effective 01/01/2019. Historical data should not be reported.

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</table>
ITEM NO / NAME: 5.06: Date of Screening MRI

PURPOSE: To specify the date of the screening MRI.

FIELD LOCATION: 120-127

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 5.01 (Mammogram Indication) is 5, then this item must be left blank.

If Item 5.05 (Screening MRI Results) is coded as 1 - 7, this item should be completed. If Item 5.05 is 8 (Pending) and the date is known, this item should be completed; otherwise this item should be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of the screening MRI. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2019).

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**ITEM NO / NAME:** 5.07: Initial Mammography Test Result

**PURPOSE:** To report the result of the initial mammogram using the American College of Radiology lexicon.

**FIELD LOCATION:** 128-129

**LENGTH:** 2

**TYPE:** Numeric - right justify

**PN ABBREVIATED FIELD:** YES

**SKIP PATTERN:** If Item 5.01 (Mammogram Indication) is 4 or 5, then this item must be left blank.

**Patient Navigation-Only Records:** If a mammogram was done or is pending, then this item must be completed.

**CONTENTS:**

- 1 = Negative (BI-RADS 1)
- 2 = Benign finding (BI-RADS 2)
- 3 = Probably benign – Initial short interval follow-up suggested (BI-RADS 3)
- 4 = Suspicious abnormality - biopsy should be considered (BI-RADS 4)
- 5 = Highly suggestive of malignancy - Appropriate action should be taken (BI-RADS 5)
- 7 = Unsatisfactory - This applies if the mammogram was technically unsatisfactory and could not be interpreted by radiologist
- 10 = Result pending
- 11 = Result unknown, presumed abnormal, mammogram from non-program funded source
- 14 = Need evaluation or film comparison (BI-RADS 0)
- 15 = Known Biopsy-Proven Malignancy (BI-RADS 6)

If result is 4, 5, 11 or 14, the Breast Final Diagnosis Section must be completed and Item 5.11 (Additional Procedures Needed to Complete Breast Cycle) must be 1 (Yes).

**EXPLANATION:** These categories are from the American College of Radiology (ACR) Breast Imaging Reporting and Database System. Please visit the ACR Web site (www.acr.org) for details on the latest lexicon.
For the purpose of this Program, an initial mammogram is the first mammogram of a screening cycle. The initial mammogram may be billed as either a screening mammogram, a diagnostic mammogram, or a 3D mammogram (as of October 2016). A diagnostic mammogram may be an initial mammogram when the patient is considered symptomatic or has an abnormal CBE and this is the first mammogram for the cycle. 3D mammograms (tomosynthesis) should be treated the same as 2D mammograms for the purposes of the MDE, including following the existing adequacy of follow-up algorithms.

A response of 3 (Probably Benign) should not be reported as the initial mammogram result unless a complete diagnostic work-up was performed (either within or outside of the program) prior to the current cycle. For example, if this is the first mammogram ever for the woman in her lifetime, then a response of 3 cannot be reported. The mammogram should be coded as a ‘4’, ‘5’ or ‘14’ and additional breast procedures should be performed to rule out cancer. Once this patient receives diagnostic testing and a Final Diagnosis is obtained, any subsequent mammogram result can be coded as 3.

A response of 7 (Unsatisfactory) indicates that the cycle should be considered complete, and a new cycle will begin with a repeat mammogram. This applies if the mammogram was technically unsatisfactory and could not be interpreted by the radiologist. It is important for Programs to monitor the use of Unsatisfactory to determine if cycles are being reported appropriately.

A response of 10 (Pending) means that either the test result is pending or that the test is scheduled to be performed. The reporting of pending results is optional. Pending results should be resolved within one year of being reported.

A response of 11 (Presumed Abnormal) should be reported when a patient receives an initial mammogram outside of the Program but the actual mammogram result cannot be obtained. The result is presumed to be abnormal; otherwise, the woman would not have been referred to the Program for diagnostic work-up. If the actual result from the outside mammogram is known, then it should be reported. The corresponding payment field, Item 5.02, should be coded as 2 (No) as long as no other procedures were paid with NBCCEDP funds. Item 5.01 (Indication for Initial Mammogram) should be reported as 3 (Non-program mammogram, Referred in for diagnostic evaluation).
A response of 14 (Need evaluation or film comparison) means that the assessment of the initial mammogram is incomplete and the radiologist requires additional breast imaging procedures, such as magnification or additional views, or a review of previous mammographic images, to determine a final interpretation.

A response of 15 (Known Biopsy-Proven Malignancy) means that findings on the initial mammogram have already been shown to be cancer by a previous biopsy. This should be a rare occurrence in our program.

Beginning January 1, 2019 (MDE version 7.0) the following Initial Mammogram Results response options were removed: 6 (Assessment Incomplete) and 13 (Film comparison required). Below is a table that outlines how to convert the Initial Mammogram Results.

<table>
<thead>
<tr>
<th>Version 6.0 Initial Mammogram Result</th>
<th>Version 7.0 Initial Mammogram Results</th>
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<tbody>
<tr>
<td>6. Assessment is Incomplete - Need additional imaging evaluation (BI-RADS 0)</td>
<td>14 Need evaluation or film comparison (BI-RADS 0)</td>
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<td>13. Film comparison required (BI-RADS 0)</td>
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<td>Removed: 6 (Assessment is Incomplete) and 13 (film comparison required)</td>
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<td></td>
<td>Added: 14 (Need evaluation or film comparison) and 15 (Known Biopsy-Proven Malignancy)</td>
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<td>Updated guidance, including converting version 6.0 results to version 7.0 results.</td>
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</table>
ITEM NO / NAME: 5.08: Date of Initial Mammogram

PURPOSE: To specify the date of the initial mammogram.

FIELD LOCATION: 130-137

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If Item 5.01 (Mammogram Indication) is a 4 or 5, then this item must be left blank.

If Item 5.07 (Initial Mammography Test Result) is coded as 1 - 5, 7, or 14 - 15, this item should be completed. If Item 5.07 is 10 (Pending) or 11 (Result unknown, presumed abnormal, mammogram from non-program funded source) and the date is known, this item should be completed; otherwise this item should be left blank.

Patient Navigation-Only Records: If the mammogram result is coded as 1 - 5, 7, 14, or 15, then this item should be completed. If Item 5.07 is 10 (Pending) or 11 (Result unknown, presumed abnormal, mammogram from non-program funded source) and the date is known, this item should be completed; otherwise this item should be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of the screening mammogram. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

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ITEM NO / NAME:  **5.09:  Clinical Breast Exam (CBE)**

PURPOSE:  The provider’s assessment of the Clinical Breast Exam.

FIELD LOCATION:  138

LENGTH:  1

TYPE:  Numeric

PN ABBREVIATED FIELD:  NO

SKIP PATTERN:  If Item 5.01 (Indication for Initial Mammogram) is 5, then this item must be left blank.

CONTENTS:  
1 = Normal/Benign findings - schedule for routine CBE in one year  
2 = Abnormality suspicious for cancer - diagnostic evaluation needed  
5 = Not performed

EXPLANATION:  This item notes the provider’s reported findings based on the Clinical Breast Exam.

These categories are not intended for use in clinical data collection; experience suggests that the categories are not sufficiently detailed to obtain valid and useful information. For more detailed clinical categories, please see the model clinical categories for CBE findings and how to categorize them into the codes for this item.

If the result of the CBE is not suspicious for cancer, code the result as a 1 (Normal/Benign findings) regardless of the time until the next routine CBE. For example, if the CBE result is benign, but a CBE is recommended in six months instead of one year, the result should still be coded as a 1 (Normal/Benign findings).

If the result of the CBE is suspicious for cancer, code the result as a 2 (Abnormality suspicious for cancer). An abnormal CBE, suspicious for cancer, regardless of the initial mammogram findings, requires additional work-up and should have the Breast Final Diagnosis Information Section of the MDEs completed.
If the woman has had a recent normal CBE, and a breast exam is not necessary during this screening visit, or if the provider indicates that a CBE is necessary during this screening visit, but is not provided, code 5 (not performed). This would include scenarios where (a) the woman refused to have the CBE performed, or (b) a trained CBE professional was not available to perform the exam.

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<tr>
<th>Version 6.0 CBE</th>
<th>Version 7.0 CBE</th>
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<tr>
<td>3. Not Needed</td>
<td>Code as:</td>
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<tr>
<td>4. Needed, but not performed at this visit</td>
<td>5. Not performed</td>
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Model Clinical Categories for CBE

At the request of the Programs, and to propose a model for the collection of the CBE data at the clinical level, the following categories were proposed by a working group of the CDC and Program participants in the spring of 1994. The use of these clinical categories on data collection tools is strongly recommended.

1 = Normal exam
2 = Benign finding (such as fibrocystic changes, diffuse lumpiness or nodularity)
3 = Discrete palpable mass (includes masses that may be cystic or solid, as well as indiscrete palpable masses)
4 = Bloody or serous nipple discharge
5 = Nipple or areolar scaliness
6 = Skin dimpling or retraction
7 = Previous normal CBE in past 12 months - CBE not done today
8 = CBE not done today - other or unknown reason
9 = CBE refused
10 = Discrete palpable mass – previously diagnosed as benign
11 = Focal pain or tenderness

Clinical categories - TRANSLATED TO - MDE categories
1, 2, 10
3, 4, 5, 6, 11
7, 8, 9

The CDC understands that category 5 and 6 are not always an indication of breast cancer. However, when these are seen, it is necessary to rule out cancer, and therefore diagnostic evaluation is needed.

Note: the above clinical categories may be collapsed, or other categories added, as deemed appropriate, as long as the translation to MDE categories is not affected.
ITEM NO / NAME: 5.10: Date of Clinical Breast Exam (CBE)

PURPOSE: To specify the date of the clinical breast exam.

FIELD LOCATION: 139-146

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 5.09 (Clinical Breast Exam) is 1 (Normal/Benign findings) or 2 (Abnormality suspicious for cancer), this item should be completed. If Item 5.09 (Clinical Breast Exam) is 5 (Not performed), or if Item 5.01 (Indication for Initial Mammogram) is 5, then this item must be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 01 to 12, DD (day) is a number from 01 to 31, and YYYY is the year of Clinical Breast Exam. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

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ITEM NO / NAME: 5.11: Additional Procedures Needed to Complete Breast Cycle

PURPOSE: To indicate the clinical recommendation for immediate additional radiologic imaging or diagnostic work-up.

FIELD LOCATION: 147

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If 5.01 (Indication for Initial Mammogram) is a 1, 2, 3, 4 or 9, then this item must be completed.

If 5.01 (Indication for Initial Mammogram) is 3 (Non-program mammogram, Referred in for diagnostic evaluation), then Item 5.11 must be 1 (Additional procedures needed or planned).

CONTENTS: 1 = Additional procedures needed or planned
2 = Additional procedures not needed or planned.
3 = Need or plan for additional procedures not yet determined.

EXPLANATION: This item was created to eliminate confusion about which women are to have immediate additional imaging or diagnostic work-up. This item should reflect the clinical recommendation for additional imaging or diagnostic work-up.

If Item 5.05 (Screening MRI Results) is 4, 5, or 7, Item 5.07 (Initial Mammography Test Results) is 4, 5, 11 or 14, or Item 5.09 (Clinical Breast Exam) is 2, then Item 5.11 (Additional Procedures) should be 1 (Needed/Planned).

If additional breast procedures are planned, based on the woman’s concerns, then this item should be completed as 1 (Needed/Planned).

If no additional imaging or diagnostic procedures are recommended, then this item should be completed as 2 (Not Needed/Planned).

A response of 3 (Not Yet Determined) should be used when the screening results are either pending or the physician has not yet indicated whether work-up is planned. This code is to be used for
administrative purposes and does not need to be added to your forms. This code can be used to create a suspense file for tracking outstanding screening results.

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ITEM NO / NAME:  **5.12: MDE Version Number**

PURPOSE: To indicate the version of the MDE that is being used for submitting data.

FIELD LOCATION: 148-149

LENGTH: 2

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: This item should always be completed.

CONTENTS: 21 = For CBE data collected through 9/30/1994
70 = For all data collected

EXPLANATION: Beginning 01/01/2019, all data collected should be reported as Version 7.0 with the exception of certain records with historical CBE data which should be reported as Version 2.1. Only a few programs will use the “21” code for this variable.

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<td>Updated guidance that all data should be reported as Version 7.0</td>
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The purpose of the Cervical Final Diagnosis and Treatment Sections is to document the final diagnosis and treatment information for women with an abnormal pelvic exam, an abnormal Pap test result or an abnormal HPV test. These items must be completed if Item 4.13 (Diagnostic Work-up Planned for Cervical Dysplasia or Cancer) is 1 (Planned).

All women who have complete diagnostic work-up should have a response for the final diagnosis, status of final diagnosis, and date of final diagnosis items.

Additionally, for some women it may be necessary to complete the status of treatment and date of treatment status items, and the Cervical Cancer Registry Data Section (Items 10.01-10.04).

If the diagnostic work-up is not complete at the time the MDE file is to be submitted to the CDC, then report all available information in the Cervical Final Diagnosis and Treatment Sections. At a minimum, however, Item 6.01 (Status of Final Diagnosis) should be reported as 2 (Work-up pending). When the remaining diagnostic work-up information is obtained the final diagnosis should be included in the next MDE submission.

Beginning January, 1, 2009 Programs are asked to work with their State Central Cancer Registry to collect and report specific North American Association of Central Cancer Registries (NAACCR) data items for records with a Final Diagnosis of invasive cervical cancer. This collaboration should include records for women screened beginning 01/01/2004 to present.
ITEM NO / NAME: 6.01: Status of Final Diagnosis

PURPOSE: To specify the status of the cervical final diagnosis.

FIELD LOCATION: 150

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: This item should always be completed when Item 4.13 (Diagnostic Work-up Planned for Cervical Dysplasia or Cancer) is 1 (Planned).

If a response of 1 (Work-up Complete) is indicated, then Items 6.02 (Final Diagnosis) and 6.04 (Date of Final Diagnosis) must be completed.

CONTENTS: 1 = Work-up Complete
2 = Work-up Pending
3 = Lost to Follow-up
4 = Work-up Refused
9 = Irreconcilable

EXPLANATION: A status of 1 (Work-up Complete) indicates that the diagnostic testing is complete, and that the final diagnosis and date of final diagnosis are known.

A status of 2 (Work-up Pending) indicates that not all of the planned diagnostic tests have been completed and therefore a final diagnosis has not yet been determined. A record should not be pending for more than one year. Such a record should be reviewed for additional information and appropriately updated.

A status of 3 (Lost to Follow-up) should be reported if prior to the initiation or completion of diagnostic work-up a woman moves to a location beyond the Program’s range of service delivery (e.g. to another country), or she cannot be located by the Program (e.g. moved).

Lost to Follow-up should be reported when tracking efforts have been attempted in accordance with the Program’s written protocol but were unsuccessful. While such cases are simply reported to
the CDC as 3 (Lost to Follow-up) in the MDE file, Programs should track more detailed information about each "lost" case.

If a woman dies prior to the initiation or completion of diagnostic work-up, the status should be indicated as 3 (Lost to Follow-up).

A status of 4 (Work-up Refused) should be reported if a woman severs her relationship with the Program. For example, a woman may decline the recommended diagnostic work-up; or she may choose to have the diagnostic work-up performed by a provider outside of the Program, and all efforts by the Program to obtain information about the work-up performed and the final diagnosis have been exhausted. Again, while such cases are simply reported to the CDC as 4 (Work-up Refused) in the MDE file, Programs should track more detailed information about each "refused" case.

CDC realizes that in many cases attempts to contact a woman continue after a record has been closed as lost to follow-up or refused. In the event that these efforts are successful and the woman returns to the Program for diagnostic follow-up, a new screening cycle should be started.

A status of 9 (Irreconcilable) should be used to code records for which after clinical review it was determined that there was no sufficient way to translate the clinical scenario into the MDE data record. For example, a clinician might refer a woman who had an abnormal Pap test result for short-term follow-up instead of following the clinical guidelines for immediate diagnostic work-up. In such cases, after case management review, Item 4.13 (Diagnostic Work-up Planned) should be modified to indicate “1” (Work-up Planned) and Item 6.01 (Status of Final Diagnosis) should be coded as “9” to indicate a cycle that has been reviewed and subsequently closed with an irreconcilable status.

It is recommended that Programs do not include irreconcilable status of final diagnosis on their MDE 7.0 data collection forms for providers to select. The intent of irreconcilable status of final diagnosis is for administrative use at your Program’s central data location, and not at the provider level. Its intended use is to help Programs manage the records in the Audit Feedback Reports that need to be reviewed and reconciled. However, records closed using an irreconcilable status of final diagnosis will still be regarded as records with incomplete follow-up in analyses of completeness.
Final diagnosis is an important outcome measure for the NBCCEDP. Thus it is critical that these data are complete, timely, and accurate.

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ITEM NO / NAME:  6.02: Final Diagnosis

PURPOSE: To specify the cervical final diagnosis.

FIELD LOCATION: 151

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: YES

SKIP PATTERN: This item should always be completed when Item 4.13 (Diagnostic Work-up Planned for Cervical Dysplasia or Cancer) is 1 (Planned) and Item 6.01 (Status of Final Diagnosis) is 1 (Work-up Complete).

Patient Navigation-Only Records: If diagnostic workup was performed for cervical cancer, then this item should be completed. Otherwise, leave blank.

CONTENTS:

1 = Normal/Benign reaction/Inflammation
2 = HPV/Condylomata/Atypia
3 = CIN1/Mild dysplasia (biopsy diagnosis)
4 = CIN2/Moderate dysplasia (biopsy diagnosis)
5 = CIN3/Severe dysplasia/Carcinoma in situ (stage 0) or Adenocarcinoma in situ of the cervix (AIS) (biopsy diagnosis)
6 = Invasive cervical carcinoma (biopsy diagnosis)
7 = Other
8 = Low grade SIL (biopsy diagnosis)
9 = High grade SIL (biopsy diagnosis)

EXPLANATION: Low grade SIL and High grade SIL are not commonly used biopsy diagnoses; however, some pathologists use this terminology when reporting cervical biopsy results. These codes are alternatives to diagnoses 2-5 above and only one final diagnosis should be reported in a record. Codes 8 and 9 are provided to allow the Programs flexibility in reporting these results.

The term “invasive cervical carcinoma” is meant to refer to histologic characteristics of tumors found primarily within the cervix.

Final diagnoses of Adenocarcinoma of the cervix, Invasive Adenocarcinoma of the cervix, or squamous cell carcinoma of the cervix should be reported as 6 (Invasive cervical carcinoma) in the
MDE file. These are invasive cervical carcinoma diagnoses that require treatment and should be reported to the Cancer Registry.

Final diagnoses of Adenocarcinoma in situ (AIS) of the cervix or squamous cell carcinoma in situ of the cervix should be reported as 5 (CIN3/Severe dysplasia/CIS/AIS) in the MDEs. AIS of the cervix is an in situ pre-cancerous condition that requires treatment.

Cancers of the vagina, vulva, ovary, uterus or endometrium detected during cervical screening should only be reported as a final diagnosis of 7 (Other) when the woman does not have a cervix. If the woman has a cervix, then the Final Diagnosis should reflect her cervical findings. For example, if the cervical diagnosis is “Normal”, but in addition a diagnosis of VAIN was reported, then the Final Diagnosis should be reported as 1 (Normal). Your Program may collect the non-cervical finding, but it should not be reported in the MDEs.

In the event that the NBCCEDP diagnosis is confirmed by the cancer registry and the Program to be a diagnosis other than cervical cancer, update Item 6.02 (Cervical Final Diagnosis) to 1 (Normal/Benign reaction/Inflammation) and Items 10.01 – 10.04 should be blank.

Melanoma, which is a skin-based cancer that can occur anywhere, and lymphoma and leukemia, which are lymphatic and blood system cancers, do not typically reflect cervical findings and should not be reported in the MDEs as 7 (Other) cervical final diagnoses. If the cervical findings are “normal”, then the cervical final diagnosis should be reported as 1 (Normal/Benign reaction/Inflammation).

Cervical lesions which are found to be a metastasis of a tumor from a different primary site (e.g. metastasis of an ovarian tumor in the cervix) should not be reported in the MDEs as 7 (Other) cervical final diagnoses. If the cervical findings are “normal”, then the cervical final diagnosis should be reported as 1 (Normal/Benign reaction/Inflammation). Your Program may collect information about the metastasis, but it should not be reported in the MDEs.

Sarcomas that are of a histologic type of primary cancer that occurs in the cervix should be considered invasive cervical carcinoma. Item 6.02 should be reported as 6 (Invasive cervical carcinoma) in the MDE file, and treatment data should be reported.
In the event that a second diagnosis of cervical cancer is reported for a woman, the Program should share the necessary information with its Cancer Registry to determine if the cancer is a new primary or a recurrence. Both new primaries and recurrences should be reported in the MDE file. Recurrences should be documented in detail in the Program’s data system.

Final diagnosis is an important outcome measure for the NBCCEDP. Thus it is critical that these data are complete, timely, and accurate.

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ITEM NO / NAME: **6.03: Final Diagnosis - Other**

PURPOSE: To specify an "other" cervical final diagnosis.

FIELD LOCATION: 152-171

LENGTH: 20

TYPE: Character - left justify

PN ABBREVIATED FIELD: YES

SKIP PATTERN: If item 6.02 (Final Diagnosis) is 7 (Other), then this item should be completed; otherwise this item should be left blank.

**Patient Navigation-Only Records:** If item 6.02 (Final Diagnosis) is 7 (Other), then this item should be completed. Otherwise, leave blank.

CONTENTS: This is a free text item.

EXPLANATION: This item should contain only final diagnosis information and not include treatment information. Examples of diagnoses that may be included are *cervical* fibroids and *cervical* polyps. Vaginal intraepithelial neoplasia (VAIN) or cancers of the vagina, vulva, ovary, uterus or endometrium may be reported in this item for women who do not have a cervix.

Items that should not be reported as Other Final Diagnoses include chronic cervicitis, uterine fibroids, or ovarian cysts. Programs should also refrain from including Pap test results, pregnancies, follow-up recommendations, and non-descriptive results such as "other pelvic abnormalities" or "unknown" diagnoses.

Please use this item appropriately. Reclaiming inappropriate "Other" responses that should be reported in Item 6.02 is time-consuming and could potentially result in the loss of valuable data.

EXAMPLE: If final diagnosis is cervical polyps, then report Item 6.02 as 7 (Other) and report Item 6.03 as "cervical polyps."
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ITEM NO / NAME:  **6.04: Date of Final Diagnosis**

PURPOSE: To specify date of final diagnosis.

FIELD LOCATION: 172-179

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 6.01 (Status of Final Diagnosis) = 1 (Work-up Complete), 3 (Lost to Follow-up), 4 (Work-up Refused) or 9 (Irreconcilable), this item should be completed; otherwise this item should be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of final diagnosis. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

EXPLANATION: This item is used for reporting the date that the clinical diagnosis was made, or the date on which the clinical decision was made that no cervical cancer is present. If Item 6.01 (Status of Final Diagnosis) is 1 (Work-up Complete), then report the date of the diagnostic procedure that either confirmed the final diagnosis of cancer or not cancer. If more than one procedure was performed, then use the date of the procedure that provided the definitive diagnosis.

If Item 6.01 (Status of Final Diagnosis) is 3 (Lost to Follow-up), 4 (Work-up Refused) or 9 (Irreconcilable), then the Date of Final Diagnosis must be completed with an administrative closeout date.

Each Program is expected to have a "Lost to Follow-up Policy" which outlines the number and types of attempts that the Program should make to contact a woman before she is declared lost to follow-up. The date of final diagnosis that is reported for a lost to follow-up case should be the date that the policy guidelines were satisfied.

Similarly, each Program should have a policy that outlines the requirements for determining that a woman has refused follow-up
services. The date of final diagnosis that is reported for a "Refused" case should be the date that the policy guidelines are satisfied.

The administrative closeout date should not be interpreted as a cessation of attempts to return the woman for appropriate care. CDC realizes that in many cases attempts to contact a woman continue well beyond this administrative date. In the event that these efforts are successful and the woman returns to the Program for diagnostic follow-up, a new screening cycle should be started.

If a woman dies before the diagnostic work-up is either started or completed, then report the date of death as the administrative close-out date for this item.

The date of final diagnosis for records with 9 (Irreconcilable) reported as the status of final diagnosis should be the date on which the Program determines via internal review of a record that there was no sufficient way to translate the clinical scenario into a complete MDE record, and that the record will remain incomplete. For example, a clinician might refer a woman for short-term follow-up instead of following the clinical guidelines for immediate diagnostic work-up.

The date of final diagnosis is important outcome information for the NBCCEDP. Program measures such as the time from screening to final diagnosis and time from final diagnosis to treatment initiation are calculated using this date.

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ITEM NO / NAME: 7.01: Status of Treatment

PURPOSE: To specify the status of standard or conventional treatment for precancerous cervical lesions and invasive cervical carcinoma.

FIELD LOCATION: 180

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 6.02 (Final Diagnosis) is 4 (CIN2), 5 (CIN3), 6 (Invasive Cervical Carcinoma), or 9 (High grade SIL), then complete Items 7.01 and 7.02.

If Item 6.02 (Final Diagnosis) is 2 (HPV/Condylomata/Atypia), 3 (CIN1), 7 (Other), or 8 (Low grade SIL), then Items 7.01 and 7.02 MAY be completed.

If Item 6.02 (Final Diagnosis) is 1 (Normal/Benign reaction/Inflammation), then Items 7.01 and 7.02 should be left blank.

CONTENTS: 1 = Treatment Started
2 = Treatment Pending
3 = Lost to Follow-up
4 = Treatment Refused
5 = Treatment Not Needed

EXPLANATION: The fact that a woman is referred for standard treatment is not sufficient confirmation that treatment has been started. A woman should be classified as having started treatment only after the Program has confirmed that a plan for standard treatment of the cancer or pre-cancerous lesion has been developed and started.

A status of 3 (Lost to Follow-up) should be reported if following a diagnosis but prior to the initiation of treatment a woman moves to a location beyond the Program's range of treatment services (e.g. to another state or country); or when tracking efforts have been attempted in accordance with the Program's written protocol but the woman cannot be located. A status of 3 (Lost to Follow-up) should also be reported if a woman dies prior to the initiation of treatment.
While such cases are simply reported to the CDC as 3 (Lost to Follow-up) in the MDE file, Programs should track more detailed information about each case.

A status of 4 (Treatment Refused) should be reported if a woman severs her relationship with the Program following diagnosis but prior to the initiation of treatment; or in the event that a woman chooses a form of non-standard or alternative treatment. For the purpose of the NBCCEDP, the CDC requires the reporting of standard or conventional treatments only. Note however that treatment using experimental drugs, such as those used in clinical trials, may be reported as 1 (Treatment Started).

A status of 5 (Treatment Not Needed) should be reported in instances where the clinician and the woman jointly agree that treatment of the cancer or pre-cancerous lesion would adversely affect the woman’s quality of life. This may occur, for example, in cases of late or end stage cancers.

A status of 5 (Treatment Not Needed) may also be reported in cases where young women (under 30 years of age) receive short-term follow-up care for CIN2 final diagnoses.

A status of 5 (Treatment Not Needed) should not be used to indicate that treatment is not needed for final diagnoses of 1 (Normal/Benign reaction/Inflammation), 2 (HPV/Condylomata/Atypia), 3 (CIN1), 7 (Other), or 8 (Low grade SIL). For those final diagnoses the status of treatment should be left blank.

In some instances, a diagnostic procedure may also constitute standard treatment. In such cases, the procedure should be reported as a cervical diagnostic procedure. Item 6.01 (Status of Final Diagnosis) should be reported as 1 (Work-up Complete); and a Final Diagnosis and Date of Final Diagnosis should be reported.

Item 7.01 (Status of Treatment) should be 1 (Treatment Started), and Item 7.02 (Date of Treatment Status) should be the date of the procedure. In most of these instances, the Date of Final Diagnosis and the Date of Treatment Status will be the same.

The CDC conferred with Registry staff to obtain a list of standard treatment options for CIN2/CIN3/CIS or Invasive Cervical Carcinoma:
MDE Item Descriptions
Section 7: Cervical Cancer Treatment Information
(Cervical Final Diagnosis and Treatment Sections)

- Photodynamic therapy (PDT)
- Electrocautery / Cauterization
- Cryosurgery
- Laser surgery
- Diathermy
- Loop Electrode Excision Procedure (LEEP)
- Cone biopsy or conization
- Removal of cervical stump; cervicectomy; trachelectomy
- Hysterectomy / Radical Hysterectomy
- Radiation Therapy; Branch Therapy
- Bilateral Salpingo-Oophorectomy (removal of both ovaries)
- Chemotherapy
- Pelvic Exenteration

Status of Treatment is an important outcome measure for the NBCCEDP. It is important to know the percentage of women diagnosed with cervical dysplasia or cancer that have started standard treatment. Thus, it is critical that these data are complete, timely, and accurate.

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ITEM NO / NAME:  **7.02: Date of Treatment Status**

PURPOSE:  To specify the date of treatment status.

FIELD LOCATION:  181-188

LENGTH:  8

TYPE:  Date - MMDDYYYY format

PN ABBREVIATED FIELD:  NO

SKIP PATTERN:  If Item 7.01 (Status of Treatment) is 1 (Treatment Started), enter MMDDYYYY, the date that treatment of cancer or precancerous lesion began.

If Item 7.01 (Status of Treatment) is 2 (Treatment Pending), then blank fill.

If Item 7.01 (Status of Treatment) is 3 (Lost to Follow-Up), 4 (Treatment Refused), or 5 (Treatment Not Needed), then enter MMDDYYYY, the date of administrative closeout.

CONTENTS:  An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of treatment status. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

EXPLANATION:  If Item 7.01 (Status of Treatment) is 1 (Treatment Started), then report the date on which the woman began standard treatment.

If Item 7.01 (Status of Treatment) = 3 (Lost to follow-up), 4 (Treatment Refused) or 5 (Treatment Not Needed), then the Date of Treatment Status must be completed with an administrative closeout date.

Each Program is expected to have a “Lost to Follow-up Policy” which outlines the number and types of attempts that the Program should make to contact a woman before she is declared lost to follow-up. The date of treatment status that is reported for a lost to follow-up case should be the date that the policy guidelines are satisfied. This is the administrative closeout date for the record.
and should not be interpreted as a cessation of attempts to have the woman return for appropriate care.

If a woman dies before treatment is initiated, then enter the date of death as the administrative closeout date for this item.

Similarly, each Program should have a policy that outlines the requirements for determining that a woman has refused treatment. The date of treatment status that is reported for a "refused" case should be the date that the policy guidelines are satisfied.

The date of treatment status for records with a 5 (Treatment Not Needed) status of treatment should be the date on which the clinician and the patient jointly agree not to pursue treatment. This may occur, for example, in cases of late or end stage cancers; or cases of CIN2 in young women (under 30 years of age).

The date of treatment status is an important outcome measure for the NBCCEDP. Program measures such as time from diagnosis to treatment are calculated using this date. Thus it is critical that these data are complete and accurate.

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The purpose of the Additional Breast Procedures Section is to document the final diagnosis and treatment information for women with abnormal mammogram results or abnormal clinical breast exam results. These items must be completed if Item 5.11 (Additional Procedures Needed to Complete Breast Cycle) is 1 (Needed/Planned).

All women who have complete diagnostic work-up should have a response for the final diagnosis, status of final diagnosis/imaging, and date of final diagnosis/imaging items.

Furthermore, for some women it may be necessary to complete the Status of Treatment and Date of Treatment Status items, as well as the Breast Cancer Registry Data Section (Items 11.01-11.04).

If the diagnostic work-up is not complete at the time the MDE file is to be submitted to the CDC, then report all available information in the Additional Breast Procedures Section. At a minimum, however, Item 8.01 (Status of Final Diagnosis/Imaging) should be reported as 2 (Work-up pending). When the remaining diagnostic work-up information is obtained the final diagnosis should be included in the next MDE submission.

Beginning January, 1, 2009 Programs are asked to work with their State Central Cancer Registry to collect and report specific North American Association of Central Cancer Registries (NAACCR) data items for records with a Final Diagnosis of in situ or invasive breast cancer. This collaboration should include records for women screened beginning 01/01/2004 to present.
ITEM NO / NAME: 8.01: Status of Final Diagnosis/Imaging

PURPOSE: To specify the status of the breast final diagnosis or imaging.

FIELD LOCATION: 189

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: This item should always be completed when Item 5.11 (Additional Procedures Needed to Complete Breast Cycle) is 1 (Needed/Planned).

If a response of 1 (Work-up Complete) is indicated, then Items 8.02 (Final Diagnosis) and 8.03 (Date of Final Diagnosis/Imaging) must be completed.

CONTENTS: 1 = Work-up Complete
2 = Work-up Pending
3 = Lost to Follow-up
4 = Work-up Refused
9 = Irreconcilable

EXPLANATION: A status of 1 (Work-up Complete) indicates that the diagnostic testing is complete, and that the final diagnosis and date of final diagnosis are known.

A status of 2 (Work-up Pending) indicates that not all of the planned diagnostic tests have been completed and therefore a final diagnosis has not yet been determined. A record should not be pending for more than one year. Such a record should be reviewed for additional information and appropriately updated.

A status of 3 (Lost to Follow-up) should be reported if prior to the initiation or completion of diagnostic work-up a woman moves to a location beyond the Program’s range of service delivery (e.g. to another country), or she cannot be located by the Program (e.g. moved).

Lost to Follow-up should be reported when tracking efforts have been attempted in accordance with the Program’s written protocol,
but were unsuccessful. While such cases are simply reported to the CDC as “Lost” in the MDEs, Programs should track more detailed information about each “lost” case.

If a woman dies prior to the initiation or completion of diagnostic work-up, the status should be indicated as 3 (Lost to Follow-up).

A status of 4 (Work-up Refused) should be reported if a woman severs her relationship with the Program. For example, a woman may decline the recommended diagnostic work-up; or she may choose to have the diagnostic work-up performed by a provider outside of the Program, and all efforts by the Program to obtain information about the work-up performed and the final diagnosis have been exhausted. Again, while such cases are simply reported to the CDC as 4 (Work-up Refused) in the MDE file, Programs should track more detailed information about each “refused” case.

CDC realizes that in many cases attempts to contact a woman continue after a record has been closed as lost to follow-up or refused. In the event that these efforts are successful and the woman returns to the Program for diagnostic follow-up, a new screening cycle should be started.

A status of 9 (Irreconcilable) should be used to code records for which after clinical review it was determined that there was no sufficient way to translate the clinical scenario into the MDE data record. For example, a clinician might refer a woman who had an abnormal CBE or initial mammogram for short-term follow-up instead of following the clinical guidelines for immediate diagnostic work-up. In such cases, after case management review, Item 5.11 (Additional Procedures Needed to Complete Breast Cycle) should be modified to indicate “1” (Additional procedures needed or planned) and 8.01 (Status of Final Diagnosis/Imaging) should be coded as “9” to indicate a cycle that has been reviewed and subsequently closed with an irreconcilable status.

It is recommended that Programs do not include irreconcilable status of final diagnosis on their MDE 7.0 data collection forms for providers to select. The intent of irreconcilable status of final diagnosis is for administrative use at your Program’s central data location, and not at the provider level. Its intended use is to help Programs manage the records in the Audit Feedback Reports that need to be reviewed and reconciled. However, records closed using an irreconcilable status of final diagnosis will still be regarded as records with incomplete follow-up in analyses of completeness.
Final diagnosis is an important outcome measure for the NBCCEDP. Thus it is critical that these data are complete, timely, and accurate.

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**ITEM NO / NAME:** 8.02: Final Diagnosis

**PURPOSE:** To specify breast final diagnosis.

**FIELD LOCATION:** 1 90

**LENGTH:** 1

**TYPE:** Numeric

**PN ABBREVIATED FIELD:** YES

**SKIP PATTERN:** This item should always be completed when Item 5.11 (Additional Procedures Needed to Complete Breast Cycle) is 1 (Needed/Planned) and Item 8.01 (Status of Final Diagnosis/Imaging) is 1 (Work-up Complete).

**Patient Navigation-Only Records:** If diagnostic workup was performed for breast cancer, then this item should be completed. Otherwise, leave blank.

**CONTENTS:**

1 = Carcinoma in situ, Other*
2 = Invasive Breast Cancer
3 = Breast Cancer not diagnosed
4 = Lobular Carcinoma in situ (LCIS) - Stage 0
5 = Ductal Carcinoma in situ (DCIS) - Stage 0

*Category (1) - CIS, Other is not a current reporting option for Final Diagnosis. It was used to report CIS diagnoses prior to 10/01/1999.

**EXPLANATION:**

The CDC is aware that there are some rare instances where the Final Diagnosis may be both DCIS and LCIS. In these cases, the Final Diagnosis should be reported and treated as DCIS.

If a woman receives a final imaging outcome such that no further diagnostic procedures are required, then this item should be reported as 3 (Breast Cancer not diagnosed).

If multiple primary tumors are detected in one screening, then report the most serious diagnosis. For example, if a woman is diagnosed with both in situ and invasive breast cancer, then report the invasive cancer as the final diagnosis.
In the event that the NBCCEDP diagnosis is confirmed by the cancer registry and the Program to be a diagnosis other than breast cancer, update Item 8.02 (Breast Final Diagnosis) to 3 (Breast cancer not diagnosed) and Items 11.01 – 11.04 should be blank.

The term “invasive breast cancer” is meant to refer to histologic characteristics of tumors found primarily within the breast; most specifically, glandular tumors. However, there are occasions when the cancer may include connective tissue, etc. Melanoma is a skin-based cancer that can occur anywhere, and it should be reported as 3 (Breast Cancer Not Diagnosed) in the MDEs. Lymphoma and leukemia are lymphatic and blood system cancers and they should be reported as 3 (Breast Cancer Not Diagnosed) in the MDEs.

Breast cancers that are found to be a metastasis of a tumor at a different primary site (e.g. metastasis of a lung tumor in the breast) should be reported as 3 (Breast Cancer Not Diagnosed) in the MDEs.

Sarcomas that are generally considered to have primary origin in the breast should be reported as 2 (Invasive Breast Cancer) in the MDEs, and treatment data should be reported.

In the event that a second diagnosis of breast cancer is reported for a woman, the Program should share the necessary information with its Cancer Registry to determine if the cancer is a new primary or a recurrence. Both new primaries and recurrences should be reported in the MDE file. Recurrences should be documented in detail in the Program's data system.

Final diagnosis is an important outcome measure for the NBCCEDP. Thus it is critical that these data are complete, timely, and accurate.

For assistance in mapping specific International Classification of Disease for Oncology (ICD-O) morphology codes to the MDE Final Diagnosis categories, please refer to the following Surveillance, Epidemiology, and End Results Program (SEER) coding manuals:

Multiple Primary and Histology Coding Rules Manual (for cases diagnosed 01/01/2007 – 01/01/2017): https://seer.cancer.gov/tools/mphrules/download.html
2018 Breast Solid Tumor coding rules (for cases diagnosed 01/01/2018 or later):

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ITEM NO / NAME: 8.03: Date of Final Diagnosis / Imaging

PURPOSE: To specify date of final diagnosis or imaging.

FIELD LOCATION: 191-198

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 8.01 (Status of Final Diagnosis/Imaging) = 1 (Work-up Complete), 3 (Lost to Follow-up), 4 (Work-up Refused) or 9 (Irreconcilable), then this item should be completed; otherwise this item should be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of final diagnosis. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

EXPLANATION: This item is for reporting of the date that the clinical diagnosis is made, or the date on which the clinical decision is made that no breast cancer is present. If Item 8.01 (Status of Final Diagnosis/Imaging) is 1 (Work-up Complete), then report the date of the diagnostic procedure that either confirmed the final diagnosis of cancer or the date that breast cancer was ruled out as the final diagnosis. If more than one procedure was performed, then use the date of the procedure that provided the definitive diagnosis.

If Item 8.01 (Status of Final Diagnosis) is 3 (Lost to Follow-up), 4 (Work-up Refused) or 9 (Irreconcilable), then the (Date of Final Diagnosis/Imaging) item must be completed with an administrative closeout date.

Each Program is expected to have a “Lost to Follow-up Policy” which outlines the number and types of attempts that the Program should make to contact a woman before she is declared lost to follow-up. The date of final diagnosis that is reported for a lost to follow-up case should be the date that the policy guidelines are satisfied.
Similarly, each Program should have a policy that outlines the requirements for determining that a woman has refused follow-up services. The date of final diagnosis that is reported for a “Refused” case should be the date that the policy guidelines are satisfied.

The administrative closeout date should not be interpreted as a cessation of attempts to return the woman for appropriate care. CDC realizes that in many cases attempts to contact a woman continue well beyond this administrative date. In the event that these efforts are successful and the woman returns to the Program for diagnostic follow-up, a new screening cycle should be started.

If a woman dies before the diagnostic work-up is either started or completed, then enter the date of death as the administrative closeout date for this item.

The date of final diagnosis for records with 9 (Irreconcilable) reported as the status of final diagnosis should be the date on which the Program determines via internal review of a record that there was no sufficient way to translate the clinical scenario into a complete MDE record, and that the record will remain incomplete. For example, a clinician might refer a woman for short-term follow-up instead of following the clinical guidelines for immediate diagnostic work-up.

The date of final diagnosis is important outcome information for the NBCCEDP. Program measures such as the time from screening to final diagnosis and time from final diagnosis to treatment initiation are calculated using this date.

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ITEM NO / NAME: 9.01: Status of Treatment

PURPOSE: To specify status of standard or conventional treatment for breast cancer.

FIELD LOCATION: 199

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 8.02 (Final Diagnosis) is 1 (CIS, Other), 2 (Invasive), or 5 (DCIS), then complete Item 9.01 (Status of Treatment) and Item 9.02 (Date of Treatment Status.)

If Item 8.02 (Final Diagnosis) is 4 (LCIS), then items 9.01 and 9.02 may be completed.

If Item 8.02 (Final Diagnosis) is 3 (Not Diagnosed), then this items 9.01 and 9.02 should be left blank.

CONTENTS: 1 = Treatment Started
2 = Treatment Pending
3 = Lost to Follow-up
4 = Treatment Refused
5 = Treatment Not Needed

EXPLANATION: The fact that a woman is referred for standard treatment is not sufficient confirmation that treatment has been started. A woman should be classified as having started treatment only after the Program has confirmed that a plan for standard treatment of the cancer has been developed and started.

A status of 3 (Lost to Follow-up) should be reported if following a diagnosis but prior to the initiation of treatment a woman moves to a location beyond the Program’s range of treatment services (e.g. to another state or country), or she cannot be located (e.g. moved).

Lost to Follow-up should be reported when tracking efforts have been attempted in accordance with the Program’s written protocol, but were unsuccessful. While such cases are simply reported to the CDC as “Lost” in the MDEs, Programs should track more
detailed information about each case. If a woman dies prior to the initiation of treatment, the status should be reported as 3 (Lost to Follow-up).

A status of 4 (Treatment Refused) should be reported if a woman severs her relationship with the Program following diagnosis but prior to the initiation of treatment; or In the event that a woman chooses a form of non-standard or alternative treatment. For the purpose of the NBCCEDP, CDC requires the reporting of standard or conventional treatments only. Note however that treatment using experimental drugs, such as those used in clinical trials, may be reported as 1 (Treatment Started).

A status of 5 (Treatment Not Needed) should be reported in instances where the clinician and the woman jointly agree that treatment of the cancer would adversely affect the woman’s quality of life. This may occur, for example, in cases of late or end stage cancers.

A status of 5 (Treatment Not Needed) should not be used to indicate that treatment is not needed for final diagnoses of 3 (Breast cancer not diagnosed) or 4 (Lobular Carcinoma in Situ).

In some instances, a diagnostic procedure may also constitute standard treatment. Item 8.01 (Status of Final Diagnosis/Imaging) should be reported as 1 (Work-up Complete); and a Final Diagnosis and Date of Final Diagnosis should be reported. Item 9.01 (Status of Treatment) should be 1 (Treatment Started), and Item 9.02 (Date of Treatment Status) should be the date of the procedure. In most of these instances, the Date of Final Diagnosis and the Date of Treatment Status will be the same.

The CDC conferred with Registry staff to obtain a list of standard treatment options for in situ and Invasive Breast Cancer:

- Mastectomy
- Lumpectomy; excisional biopsy; tylectomy
- Re-excision of the biopsy site
- Wedge resection
- Quadrantectomy
- Radiation Therapy
- Chemotherapy
- Hormonal Therapy (e.g. Tamoxifen)
- Immunotherapy (e.g. Herceptin)
- Bone Marrow Transplant
• Axillary lymph node dissection

Status of Treatment is an important outcome measure for the NBCCEDP. It is important to know the percentage of women diagnosed with breast cancer that have started treatment. Thus it is critical that these data are complete, timely, and accurate.

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ITEM NO / NAME:  **9.02: Date of Treatment Status**

PURPOSE: To specify date of treatment status.

FIELD LOCATION: 200-207

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 9.01 (Status of Treatment) is 1 (Treatment Started), 3 (Lost to Follow-up), 4 (Refused), or 5 (Treatment Not Needed), then this item should be completed; otherwise this item should be left blank.

CONTENTS: An 8-digit numeric item of the form MMDDYYYY, where MM (month) is a number from 1 to 12, DD (day) is a number from 1 to 31, and YYYY is the year of treatment status. If just the year is known, then blank fill the month and day. If just the year and month are known, then blank fill the day (e.g. 01_ _2011).

EXPLANATION: If Item 9.01 (Status of Treatment) is 1 (Treatment Started), then report the date on which the woman began standard treatment.

If Item 9.01 (Status of Treatment) = 3 (Lost to follow-up), 4 (Treatment Refused) or 5 (Treatment Not Needed), then the “Date of Treatment Status” item must be completed with an administrative closeout date.

Each Program is expected to have a “Lost to Follow-up Policy” which outlines the number and types of attempts that the Program should make to contact a woman before she is declared Lost to Follow-up. The date of treatment status that is reported for a "Lost to Follow-up" case should be the date that the policy guidelines are satisfied. This is the administrative closeout date for the record.

Also, if a woman dies before treatment is initiated, then enter the date of death as the administrative closeout date for this item.

Similarly, each Program should have a policy that outlines the requirements for determining that a woman has refused treatment. The date of treatment status that is reported for a "refused" case should be the date that the policy guidelines are satisfied.
The date of treatment status for records with a 5 (Treatment Not Needed) status of treatment should be the date on which the clinician and the patient jointly agree not to pursue treatment because it would adversely affect the woman’s quality of life. This may occur, for example, in cases of late or end stage cancers.

The date of treatment status is an important outcome measure for the NBCCEDP. Program measures such as time from diagnosis to treatment are calculated using this date. Thus it is critical that these data are complete and accurate.

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The Cervical and Breast Cancer Registry Data Sections are used for the reporting of stage data acquired via a State Central Cancer Registry. Cancer stage at diagnosis is an important outcome measure for a national screening program such as the NBCCEDP.

The Cervical and Breast Cancer Registry Data Sections must be completed for all women screened* beginning 01/01/2004 with a diagnosis of in situ or invasive cancer. This is the date on which the use of the Collaborative Staging (CS) System began.

*If a screening date is not available because the patient was referred directly for diagnostic follow-up, then the date of final diagnosis should be used.

Please note that melanoma, which is a skin-based cancer that can occur anywhere, and lymphoma and leukemia, which are lymphatic and blood system cancers, do not typically reflect breast and cervical findings and should not be reported in the MDEs as breast or cervical cancer diagnoses. If linkage with the State Central Cancer Registry indicates that a breast or cervical cancer diagnosis reported in the MDEs is actually a different diagnosis, and the registry data are confirmed by the Program to match the screening record, then the final diagnosis field for the record should be updated in the MDE data to indicate that breast or cervical cancer was not diagnosed and the Cancer Registry Data Section should be blank.

Sarcomas that are of a histologic type that generally has primary origin in the breast should be reported as invasive breast cancer in the MDEs, and treatment data should be reported. Sarcomas that are of a histologic type of primary cancer that occurs in the cervix should be reported as invasive cervical carcinoma in the MDEs, and treatment data should be reported.

The following sections describe the Cancer Registry data items required as part of the MDE 7.0 data set. See Appendix 10 (Guidance Document on Performing Data Linkages) for additional information about each of the required Cancer Registry data items and links to online resources.
ITEM NO / NAME: 10.01: Registry Linkage Status

PURPOSE: To indicate if the diagnosis for the woman reported in Item 8.02 (Final Diagnosis) was matched with the Program’s State Central Cancer Registry (or an equivalent data source approved by CDC).

FIELD LOCATION: 208

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 6.02 (Final Diagnosis) is 6 (Invasive Cervical Carcinoma) and the woman was screened on or after 01/01/2004, this item must be completed. Items 10.01 – 10.04 should only be completed for cervical cancers. In the event that the NBCCEDP diagnosis is confirmed by the cancer registry and the Program to be a diagnosis other than cervical cancer, update Item 6.02 (Cervical Final Diagnosis) to 1 (Normal/Benign reaction/Inflammation) and Items 10.01 – 10.04 should be blank.

CONTENTS: 1 = Linkage process pending
2 = Linkage process complete, record matched
3 = Linkage process attempted, record not matched

EXPLANATION: A status of 1 (Linkage process pending) should be used to indicate that the record has not yet been included in a linkage attempt between the Program and the State Central Cancer Registry. Items 10.02 - 10.04 should be left blank.

A status of 2 (Linkage process complete, record matched) should be used to indicate that the record has been included in a linkage attempt and has been matched to data in the State Central Cancer Registry. Items 10.02 – 10.04 must be completed.

A status of 3 (Linkage process attempted, record not matched) should be used to indicate that the record has been included in a linkage attempt but could not be matched to data in the State Central Cancer Registry. Items 10.02 – 10.04 should be left blank.

For Programs who do not have a State Central Cancer Registry with which to link, please contact your CDC Program Consultant.
with information regarding an alternative data source. You must have approval from the CDC to report data from an alternative source in the Cervical Cancer Registry Data Section.

EXAMPLE: If the Registry linkage is pending: 1.

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ITEM NO / NAME:  **10.02: Registry Date of Diagnosis**

PURPOSE: To report the date of diagnosis obtained from the state central cancer registry.

FIELD LOCATION:  209-216

LENGTH:  8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD:  NO

SKIP PATTERN: If Item 6.02 (Final Diagnosis) is reported as 6 (Invasive Cervical Carcinoma), and Item 10.01 (Registry Linkage Status) is reported as 2 (Linkage process complete, record matched), then this item should be completed; otherwise this item should be left blank.

CONTENTS: An 8-digit date item of the form MMDDYYYY, where MM (month) is a value from 01 to 12, DD (day) is a value from 01 to 31, and YYYY is the year of the diagnosis. Prior to 01/01/2010, if any part of the Registry Date of Diagnosis is unknown, 9-fill or blank-fill only that part. Beginning with NAACCR v12 on 01/01/2010, if any part of the Registry Date of Diagnosis is unknown, blank-fill (do not 9-fill) only that part.

EXPLANATION: This item should indicate the date of diagnosis [NAACCR data item # 390] obtained from the state central cancer registry.

See Appendix 10 (Guidance Document on Performing Data Linkages) for resources with additional information about Registry Date of Diagnosis.

Please note that Item 6.04 (the Date of Final Diagnosis) and Item 10.02 (Registry Date of Diagnosis) will differ in most instances.

EXAMPLE: If the Registry Date of Diagnosis is 03/28/2011: 03282011.
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ITEM NO / NAME: **10.03: Registry Summary Stage**

**PURPOSE:** To indicate the summary stage obtained from the state central cancer registry.

**FIELD LOCATION:** 217

**LENGTH:** 1

**TYPE:** Numeric

**PN ABBREVIATED FIELD:** NO

**SKIP PATTERN:** If Item 6.02 (Final Diagnosis) is reported as 6 (Invasive Cervical Carcinoma), and 10.01 (Registry Linkage Status) is reported as 2 (Linkage process complete, record matched), then this item should be completed; otherwise this item should be left blank.

**CONTENTS:**

- 0 = In situ (IS)
- 1 = Localized (L)
- 2 = Regional, direct extension only (RE)
- 3 = Regional, regional lymph nodes only (RN)
- 4 = Regional, extension and nodes (RE + RN)
- 5 = Regional, NOS (RNOS)
- 7 = Distant (D)
- 8 = Not applicable (NA)
- 9 = Unknown/unstaged (U)

**EXPLANATION:** If Item 10.01 (Registry linkage status) is reported as 2 (Linkage process complete, record matched), then report the summary stage obtained from the state central cancer registry database.

If Item 10.02 (Registry Date of Diagnosis) is ≥ 01/01/2018, report NAACCR data item # 764.

If Item 10.02 (Registry Date of Diagnosis) is = 01/01/2016 – 12/31/2017, report NAACCR data item # 759.

If Item 10.02 (Registry Date of Diagnosis) is = 01/01/2004 – 12/31/2015, report NAACCR data item # 3020.

If Item 10.02 (Registry Date of Diagnosis) is = 01/01/2001 - 12/31/2003, report NAACCR data item # 759.
If Item 10.02 (Registry Date of Diagnosis) is ≤ 12/31/2000, report NAACCR data item # 760.

See Appendix 10 (Guidance Document on Performing Data Linkages) for resources with additional information about Registry Summary Stage.

EXAMPLE: If the Registry summary stage is distant: Z

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<td>7.0</td>
<td>08/01/2019</td>
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<td>Updated skip pattern and explanation to reflect new item numbers.</td>
</tr>
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10.04: Registry Collaborative Stage (CS) – Derived AJCC Stage Group

PURPOSE: To report the appropriate CS-Derived AJCC Stage Group as indicated by the state central cancer registry.

FIELD LOCATION: 218-219

LENGTH: 2

TYPE: Numeric - right justified with leading zeroes.

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 6.02 (Final Diagnosis) is reported as 6 (Invasive Cervical Carcinoma), 10.01 (Registry Linkage Status) is reported as 2 (Linkage process complete, record matched), and Item 10.02 (Registry Date of Diagnosis) is = 01/01/2004 – 12/31/2015, then this item should be completed; otherwise this item should be left blank.

Complete the CS-Derived AJCC Stage Group 6th Edition field as available since not required by NPCR registries.

CONTENTS: Valid values for CS-Derived AJCC Stage Group fall within the range of 00 to 99.

Report the appropriate NAACCR data item that corresponds with the AJCC edition in effect at the time of diagnosis:

CS-Derived AJCC-6 Stage Group (NAACCR # 3000), 2004-2009
CS-Derived AJCC-7 Stage Group (NAACCR # 3430), 2010-2015

See Appendix 10 (Guidance Document on Performing Data Linkages) for resources with additional information about CS-Derived AJCC Stage Group.

EXPLANATION: While CS—Derived AJCC Stage Group expanded from 2-digits in the 6th Edition to 3-digits in the 7th Edition, the CDC does not plan to expand to 3-digits in the MDEs at this time. When reporting AJCC 7th edition cases from 2010 forward, the MDEs will collect the first 2-digits of the 3-digit code which provide a general classification. Programs are encouraged to consult with their IT staff/system vendor and their Cancer Registry to assess the feasibility and need to expand this field to 3-digits in their database system. Programs
are advised to truncate the 3-digit value when creating the MDE file by reporting the first two digits and dropping the last of the three digits.

Not all cancer registries collect this information. If this field is blank in the Cancer Registry, report 99 (Unknown).

EXAMPLE: If a lesion was diagnosed as a Stage II: 30

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<td>7.0</td>
<td>08/01/2019</td>
<td>Updated item number and field location. Updated skip pattern and explanation to reflect new item numbers.</td>
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</tbody>
</table>
ITEM NO / NAME: 11.01: Registry Linkage Status

PURPOSE: To indicate if the diagnosis for the woman reported in Item 8.02 (Final Diagnosis) was matched with the Program’s State Central Cancer Registry (or an equivalent data source approved by CDC).

FIELD LOCATION: 220

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 8.02 (Final Diagnosis) is 1 (Carcinoma in situ, Other), 2 (Invasive Breast Cancer), 4 (Lobular Carcinoma in situ) or 5 (Ductal Carcinoma in situ) and the woman was screened on or after 01/01/2004, then this item must be completed. Items 11.01 – 11.07 should only be completed for breast cancers. In the event that the NBCCEDP diagnosis is confirmed by the cancer registry and the Program to be a diagnosis other than breast cancer, update Item 8.02 (Breast Final Diagnosis) to 3 (Breast cancer not diagnosed) and Items 11.01 – 11.07 should be blank.

CONTENTS: 1 = Linkage process pending
2 = Linkage process complete, record matched
3 = Linkage process attempted, record not matched

EXPLANATION: A status of 1 (Linkage process pending) should be used to indicate that the record has not yet been included in a linkage attempt between the Program and the State Central Cancer Registry. Items 11.02 - 11.07 should be left blank.

A status of 2 (Linkage process complete, record matched) should be used to indicate that the record has been included in a linkage attempt and has been matched to data in the State Central Cancer Registry. Items 11.02 – 11.07 must be completed.

A status of 3 (Linkage process attempted, record not matched) should be used to indicate that the record has been included in a linkage attempt and could not be matched to data in the State Central Cancer Registry. Items 11.02 – 11.07 should be left blank.
For Programs who do not have a State Central Cancer Registry to link with, please contact your CDC Program Consultant with information regarding an alternative data source. You must have approval from the CDC to report data from an alternative source in the Cervical Cancer Registry Data Section.

As noted in Item 8.02 (Final Diagnosis) the category of (1) Carcinoma in situ, Other is appropriate for the coding of old data only; and beginning 10/01/1999 Programs were instructed to report all Carcinoma in situ cases as either 4 (LCIS) or 5 (DCIS). The MDE Edit Program identifies such records for corrective action.

However, if a record with a final diagnosis of (1) Carcinoma in situ, Other is reported on or after 01/01/2004 your Program should still attempt to match that record to the State Central Cancer Registry which can provide more specific final diagnosis information.

EXAMPLE: If the Registry linkage is pending: 1.

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</tbody>
</table>
ITEM NO / NAME: 11.02: Registry Date of Diagnosis

PURPOSE: To report the date of diagnosis obtained from the state central cancer registry.

FIELD LOCATION: 221-228

LENGTH: 8

TYPE: Date - MMDDYYYY format

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 8.02 (Final Diagnosis) is reported as 1 (Carcinoma in situ, Other), 2 (Invasive Breast Cancer), 4 (Lobular Carcinoma in situ) or 5 (Ductal Carcinoma in situ), and 11.01 (Registry Linkage Status) is reported as 2 (Linkage process complete, record matched), this item should be completed; otherwise this item should be left blank.

CONTENTS: An 8-digit date item of the form MMDDYYYY, where MM (month) is a value from 01 to 12, DD (day) is a value from 01 to 31, and YYYY is the year of the diagnosis. Prior to 01/01/2010, if any part of the Registry Date of Diagnosis is unknown, 9-fill or blank-fill only that part. Beginning with NAACCR v12 on 01/01/2010, if any part of the Registry Date of Diagnosis is unknown, blank-fill (do not 9-fill) only that part.

EXPLANATION: This item should indicate the date of diagnosis [NAACCR data item # 390] obtained from the state central cancer registry.

See Appendix 10 (Guidance Document on Performing Data Linkages) for resources with additional information about Registry Date of Diagnosis.

Please note that Item 8.03 (the Date of Final Diagnosis/Imaging) and Item 11.02 (the Registry Date of Diagnosis) will differ in most instances.

EXAMPLE: If the Registry Date of Diagnosis is 03/28/2011: 03282011.
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</table>
ITEM NO / NAME: 11.03: Registry Summary Stage

PURPOSE: To indicate the summary stage obtained from the state central cancer registry.

FIELD LOCATION: 229

LENGTH: 1

TYPE: Numeric

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 8.02 (Final Diagnosis) is reported as 1 (Carcinoma in situ, Other), 2 (Invasive Breast Cancer), 4 (Lobular Carcinoma in situ) or 5 (Ductal Carcinoma in situ), and 11.01 (Registry Linkage Status) is reported as 2 (Linkage process complete, record matched), this item should be completed; otherwise this item should be left blank.

CONTENTS: 0 = In situ (IS) 
1 = Localized (L) 
2 = Regional, direct extension only (RE) 
3 = Regional, regional lymph nodes only (RN) 
4 = Regional, extension and nodes (RE + RN) 
5 = Regional, NOS (RNOS) 
7 = Distant (D) 
8 = Not applicable (NA) 
9 = Unknown/unstaged (U)

EXPLANATION: If Item 11.01 (Registry linkage status) is reported as 2 (Linkage process complete, record matched), then report the summary stage obtained from the state central cancer registry database.

If Item 11.02 (Registry Date of Diagnosis) is ≥ 01/01/2018, report NAACCR data item # 764.

If Item 11.02 (Registry Date of Diagnosis) is = 01/01/2016 – 12/31/2017, report NAACCR data item # 759.

If Item 11.02 (Registry Date of Diagnosis) is = 01/01/2004 – 12/31/2015, report NAACCR data item # 3020.

If Item 11.02 (Registry Date of Diagnosis) is = 01/01/2001 - 12/31/2003, report NAACCR data item # 759.
If Item 11.02 (Registry Date of Diagnosis is ≤ 12/31/2000, report NAACCR data item # 760.

See Appendix 10 (Guidance Document on Performing Data Linkages) for resources with additional information about Registry Summary Stage.

EXAMPLE: If the Registry summary derived stage is localized:  

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</tbody>
</table>
ITEM NO / NAME: 11.04: Registry Collaborative Stage (CS) – Derived AJCC Stage Group

PURPOSE: To report the appropriate CS derived AJCC Stage Group as indicated by the state central cancer registry.

FIELD LOCATION: 230-231

LENGTH: 2

TYPE: Numeric - right justified with leading zeroes.

PN ABBREVIATED FIELD: NO

SKIP PATTERN: If Item 8.02 (Final Diagnosis) is reported as 1 (Carcinoma in situ, Other), 2 (Invasive Breast Cancer), 4 (Lobular Carcinoma in situ) or 5 (Ductal Carcinoma in situ), 11.01 (Registry Linkage Status) is reported as 2 (Linkage process complete, record matched), and Item 11.02 (Registry Date of Diagnosis) is = 01/01/2004 – 12/31/2015, then this item should be completed; otherwise this item should be left blank.

Complete the CS-Derived AJCC Stage Group 6th Edition field as available since not required by NPCR registries.

CONTENTS: Valid values for Registry CS-derived AJCC Stage Group fall within the range of 00 to 99.

Report the appropriate NAACCR data item that corresponds with the AJCC edition in effect at the time of diagnosis:

CS-Derived AJCC-6 Stage Group (NAACCR # 3000), 2004-2009
CS-Derived AJCC-7 Stage Group (NAACCR # 3430), 2010-2015

See Appendix 10 (Guidance Document on Performing Data Linkages) for resources with additional information about CS-Derived AJCC Stage Group.

EXPLANATION: While CS—Derived AJCC Stage Group expanded from 2-digits in the 6th Edition to 3-digits in the 7th Edition, the CDC does not plan to expand to 3-digits in the MDEs at this time. When reporting AJCC 7th edition cases from 2010 forward, the MDEs will collect the first 2-digits of the 3-digit code which provide a general classification. Programs are encouraged to consult with their IT staff/system vendor and their Cancer Registry to assess the feasibility and need...
to expand this field to 3-digits in their database system. Programs are advised to truncate the 3-digit value when creating the MDE file by reporting the first two digits and dropping the last of the three digits.

Not all cancer registries collect this information. If this field is blank in the Cancer Registry, report 99 (Unknown).

EXAMPLE: If a mass was diagnosed as a Stage II: 30

REVISION HISTORY:

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<td>Updated skip pattern and explanation to reflect new item numbers.</td>
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</tbody>
</table>
ITEM NO / NAME:  End of Record Mark

PURPOSE:  To specify the end of record.

FIELD LOCATION:  232

LENGTH:  1

EXPLANATION:  Each record should end with a carriage return-line feed (CR-LF).

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### National Breast and Cervical Cancer Early Detection Program
### Minimum Data Elements (MDE) Data Definition Table

#### Item Number | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks/Skip Patterns
--- | --- | --- | --- | --- | --- | ---
1.01 | State, Territorial, or Tribal Program | 2 | 1 | 2 | Right Justify (i.e. California = -6 and Texas = 48, where - = a blank character.) | Valid code for your program.

#### Section 1: Program, Patient, and Record Location

| Item Number | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks/Skip Patterns
--- | --- | --- | --- | --- | --- | ---
1.02 | Unique Patient ID Number | 15 | 3 | 17 | If Social Security Number (SSN) is used, it must be encoded. The ID number should be unique and constant for each patient in order to track the patient over time. This field should not contain any identifiable information, including partial names or dates. Alphanumeric (no special symbols), left justify. Alphabetic characters must be entered consistently in uppercase or lowercase for all records for each patient. |  
1.03 | Record Identifier | 8 | 18 | 25 | Right Justify. This field will be used to uniquely identify one record among many for a woman. This could be a cycle number, a visit date, or a record number. In this context, record and screening cycle have the same meaning. |  

#### Section 2: Patient Demographic Information

| Item Number | Variable Name | Column Length | Column Begin | Column End | Codes / Format / Comments | Edit Checks/Skip Patterns
--- | --- | --- | --- | --- | --- | ---
2.01 | County of Residence | 3 | 26 | 28 | FIPS Code, Right Justify. (If unknown, blank fill.) Not required if Zip Code of residence is reported. | Valid FIPS code for the county.
2.02 | State or Territory of Residence | 2 | 29 | 30 | FIPS Code, Right Justify. (If unknown, blank fill.) | Valid FIPS code for the state or territory.
<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Column Begin</th>
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<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.03</td>
<td>ZIP Code of Residence [PN Abbreviated Field]</td>
<td>5</td>
<td>31</td>
<td>35</td>
<td>Right Justify. (If unknown, blank fill) Not required if county of residence is reported.</td>
<td>Valid 5 digit numeric zip code.</td>
</tr>
<tr>
<td>2.04</td>
<td>Date of Birth [PN Abbreviated Field]</td>
<td>6</td>
<td>36</td>
<td>41</td>
<td>MMYYYY (i.e. Jan 1942 = 011942). If unknown, blank fill.</td>
<td>Check for validity, i.e. no one too old or too young at date of enrollment. See edit guidelines for dates at the end of this document.</td>
</tr>
</tbody>
</table>
| 2.05        | Hispanic or Latino Origin (self-reported) [PN Abbreviated Field] | 1             | 42           | 42         | 1. Yes  
2. No  
3. Unknown                                                                                         | Range check.            |
| 2.06.1      | Race 1 (self-reported) [PN Abbreviated Field] | 1             | 43           | 43         | 1. White  
2. Black or African American  
3. Asian  
4. Native Hawaiian or Other Pacific Islander  
5. American Indian or Alaska Native  
7. Unknown  
8. Asian/Pacific Islander (v4.1 only)*  
*8 - Asian/Pacific Islander (v4.1 only) may only be reported for data collected prior to 10/01/2002. | Range check. This race field should be populated first. If a woman self identifies more than one race, then each race identified should be reported in a separate race field. Report up to five (5) separate races.  
It is recommended that your Program no longer collect ‘Other’ race on your data collection forms. However, if your Program collects ‘Other’ as a race category, please export this to ‘7’ (Unknown) in the MDEs. |
| 2.06.2      | Race 2 (self-reported) [PN Abbreviated Field] | 1             | 44           | 44         | 1. White  
2. Black or African American  
3. Asian  
4. Native Hawaiian or Other Pacific Islander  
5. American Indian or Alaska Native  
7. Unknown | This field should be left blank, unless the woman reports more than one race. |
<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Column Begin</th>
<th>Column End</th>
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</thead>
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<td>2.06.3</td>
<td>Race 3 (self-reported)</td>
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<td>45</td>
<td>45</td>
<td>1. White</td>
<td>This field should be left blank, unless the woman reports more than two races.</td>
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<td>2. Black or African American</td>
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<td>3. Asian</td>
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<td>4. Native Hawaiian or Other Pacific Islander</td>
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<td>5. American Indian or Alaska Native</td>
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<td>7. Unknown</td>
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<tr>
<td>2.06.4</td>
<td>Race 4 (self-reported)</td>
<td>1</td>
<td>46</td>
<td>46</td>
<td>1. White</td>
<td>This field should be left blank, unless the woman reports more than three races.</td>
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<td>2. Black or African American</td>
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<td>3. Asian</td>
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<td>4. Native Hawaiian or Other Pacific Islander</td>
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<td>5. American Indian or Alaska Native</td>
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<td>7. Unknown</td>
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<tr>
<td>2.06.5</td>
<td>Race 5 (self-reported)</td>
<td>1</td>
<td>47</td>
<td>47</td>
<td>1. White</td>
<td>This field should be left blank, unless the woman reports more than four races.</td>
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<td>2. Black or African American</td>
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<td>3. Asian</td>
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<td>4. Native Hawaiian or Other Pacific Islander</td>
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<td>7. Unknown</td>
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<td>Section 3: Patient Navigation</td>
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<tr>
<td>Codes / Format / Comments</td>
<td>Data collection for this field is effective 01/01/2019. This field is asking whether PN was paid with NBCCEDP funds, not whether PN was delivered. Historical data should be coded as ‘3’ Unknown. If patient navigation is delivered (consistent with CDC policy) using NBCCEDP funds to support the navigation (e.g. reimbursement fee-for-service, paid for staff delivering PN), select ‘1’ Yes. ‘2’ No should be selected if NBCCEDP funds were not used or PN was not delivered. ‘3’ Unknown</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Section 4: Cervical Screening Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.01</strong> Previous Pap Test</td>
</tr>
<tr>
<td>Codes / Format / Comments</td>
</tr>
</tbody>
</table>

| **4.02** Date of Previous Pap Test | 6 | 50 | 55 | If "Previous Pap Test" = ‘1’ then enter MMYYYY (if known) or blank fill (if unknown). If "Previous Pap Test" = ‘2’ or ‘3’, blank fill. |
| Codes / Format / Comments | If not blank, must be a valid date. Check the skip pattern. |
### National Breast and Cervical Cancer Early Detection Program
### Minimum Data Elements (MDE) Data Definition Table

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Column Begin</th>
<th>Column End</th>
<th>Codes / Format / Comments</th>
</tr>
</thead>
</table>
| 4.03        | Indication for Pap Test| 1             | 56           | 56         | 1. Screening  
2. Surveillance  
3. Non-program Pap, Referred in for diagnostic evaluation  
4. No Pap  
5. No Cervical Service  
6. Pap after primary HPV+  
9. Unknown  

If Indication for Pap Test is ‘5’ then items 4.04 – 4.13 should be blank.

Data collection for this field is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise, code as ‘9’ (Unknown).

‘1’ (Screening) should be reported for a Pap test performed as part of a routine screening schedule. Items 4.04 – 4.13 should be reported as appropriate. Item 4.06 should be blank.

‘2’ (Surveillance) should be reported for a Pap test performed on a woman under management for a cervical abnormality (abnormal Pap or HPV) detected prior to this cycle. Items 4.04 – 4.13 should be reported as appropriate. Item 4.06 should be blank.

‘3’ (Referred) should be reported when a patient has had a Pap test performed outside of the Program, and is referred to the Program for diagnostic work-up. Referral Date (4.06) must be completed, and a valid Pap test Result should be provided: (4.07) ‘1’-’11’ or ‘14’.

‘4’ (No Pap) should be reported when the patient does not have a screening Pap test and goes directly to Diagnostic Work-up or only had a primary HPV test. Items 4.06 – 4.09 should be blank.

‘5’ (No Cervical Service) should be reported when no cervical services are provided or reported in this record, only breast services. Items 4.04 – 4.13 should be blank.

‘6’ (Pap after primary HPV+) should be reported when a Pap test is done as follow-up to a positive (other 12) primary HPV test. Items 4.04 – 4.13 should be reported as appropriate. Item 4.06 should be blank.
<table>
<thead>
<tr>
<th>Item Number</th>
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</tr>
</thead>
</table>
| 4.04        | Cervical Service Paid by NBCCEDP Funds [PN Abbreviated Field] | 1             | 57           | 57         | 1. Yes  
2. No  
3. Unknown                                                                 | Data collection for this field is effective 01/01/2019. Historical data can be reported if accurately collected; otherwise, code as ‘3’ (Unknown).  
This field should be left blank if “Indication for Pap Test” (4.03) is ‘5’.  
If Pap test, HPV test, or at least one cervical diagnostic procedure was paid by NBCCEDP Funds, then this field should be set to ‘1’ (Yes). |
| 4.05        | High Risk for Cervical Cancer       | 1             | 58           | 58         | 1. Yes  
2. No  
9. Not assessed/Unknown                                                                 | Data collection for this field is effective 01/01/2019. Historical data should be coded as ‘9’ (Unknown). This field should be left blank if “Indication for Pap Test” (4.03) is ‘5’.  
‘1’ (Yes) should be reported if risk was assessed and determined to be high risk, as defined as prior DES exposure and/or immunocompromised patients.  
‘2’ (No) should be reported if risk was assessed and not determined to be high risk  
‘9’ (Not assessed/Unknown) should be reported if risk was not assessed, family history was not taken, genetic testing was not done or if risk is unknown. |
| 4.06        | Cervical Diagnostic Referral Date   | 8             | 59           | 66         | If “Indication for Pap Test” = ‘3’, enter MMDDYYYY; otherwise leave blank                 | Data collection for this field is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise, leave blank.  
If not blank, must be a valid date. Check the skip pattern.  
See edit guidelines for skip patterns at the end of this document.  
This field should indicate the enrollment date for a patient referred in to the program for diagnostic evaluation following an abnormal Pap test provided outside of the program. |
### National Breast and Cervical Cancer Early Detection Program
#### Minimum Data Elements (MDE) Data Definition Table

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
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<th>Column End</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
</table>
| 4.07        | Result of Pap Test | 2 | 67 | 68 | 1. Negative for intraepithelial lesion or malignancy  
2. Infection/Inflammation/Reactive Changes (Beth1991)  
3. Atypical squamous cells of undetermined significance (ASC-US)  
4. Low Grade SIL (including HPV changes)  
5. Atypical squamous cells cannot exclude HSIL (ASC-H Beth2001)  
6. High Grade SIL  
7. Squamous Cell Carcinoma  
8. Atypical Glandular Cells (Beth2014)  
9. Adenocarcinoma in situ (AIS) (Beth2014)  
10. Adenocarcinoma (Beth2014)  
11. Other  
12. Unsatisfactory  
13. Result Pending  
14. Result unknown, presumed abnormal, Pap test from non-program funded source | Data collection for this field is effective 01/01/2019.  
Please reference MDE v6 to v7 Conversion Specifications in Appendix 6 to map historical data.  
This field should be left blank if "Indication for Pap Test" (4.03) is '4' or '5'.  
If the result of this Pap test is a , '5', '6', '7', '8', '9', '10', or '14' the Cervical Diagnosis Information Section MUST be completed and "Diagnostic work-up planned for cervical dysplasia or cancer" (4.13) set to '1'.  
If the result is a '1', '2', '3', or '4' and the clinician chooses to do a diagnostic work-up, the Cervical Diagnosis Information Section MUST also be completed and "Diagnostic work-up planned for cervical dysplasia or cancer" (4.13) set to '1'.  
This field should = '14' only when "Indication for Pap test" (4.03) is 3 (Non-program Pap, Referred in for diagnostic evaluation) and the actual result of the Pap test is not known. |
| 4.08        | Other Pap Test Result | 20 | 69 | 88 | If "Result of Pap Test" = '11', enter "Result" in free text format. | This field should be left blank if "Indication for Pap Test" (4.03) is '4' or '5'. |
| 4.09        | Date of Pap Test | 8 | 89 | 96 | If "Result of Pap Test" ≤ '12', enter MMDDYYYY.  
If you know the date for '13' or '14', enter MMDDYYYY, otherwise blank fill. | This field should be left blank if "Indication for Pap Test" (4.03) is '4' or '5'. |
<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>4.10</td>
<td>Indication for HPV Test</td>
<td>1</td>
<td>97</td>
<td>97</td>
<td>1. Co-Test/Screening&lt;br&gt;2. Reflex&lt;br&gt;3. Test not done&lt;br&gt;9. Unknown</td>
<td>Data collection for this field is effective 01/01/2019. For cycles before 01/01/2019 where an HPV test was not performed, code as ‘3’ (Test Not Done). Other historical data were an HPV test was done can be reported if accurately collected; otherwise code as ‘9’ (Unknown).&lt;br&gt;This field should be left blank if “Indication for Pap Test” (4.03) is ‘5’.&lt;br&gt;‘1’ (Co-Test/Screening) should be reported if HPV test is performed alone or in combination with a Pap test as part of cervical cancer screening.&lt;br&gt;‘2’ (Reflex) should be reported if a HPV test is performed as a follow-up test after a screening Pap test.&lt;br&gt;‘3’ (Test not done)</td>
</tr>
<tr>
<td>Item Number</td>
<td>Variable Name</td>
<td>Column Length</td>
<td>Column Begin</td>
<td>Column End</td>
<td>Codes / Format / Comments</td>
<td>Edit Checks/Skip Patterns</td>
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</tr>
</tbody>
</table>
| 4.11        | HPV Test Result [PN Abbreviated Field] | 1             | 98           | 98         | 1. Positive with genotyping not done/unknown  
2. Negative  
4. Positive with positive genotyping  
5. Positive with negative genotyping  
9. Unknown | Data collection for this field is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise, leave blank.  
This field should be left blank if “Indication for Pap Test” (4.03) is ‘5’.  
This field should be left blank if “Indication for HPV Test” (4.10) is ‘3’.  
‘1’ should be reported if HPV test was positive and genotyping was not done or unknown.  
‘2’ should be reported if HPV test was negative.  
‘4’ should be reported if HPV test was positive and genotyping identifies type 16 or 18.  
‘5’ should be reported if HPV test was positive and genotyping does not identify type 16 or 18. |
| 4.12        | Date of HPV Test [PN Abbreviated Field] | 8             | 99           | 106        | If “HPV Test Result” = ‘1’-‘5’ or ‘9’, then enter MMDDYYYY  
Date of HPV Test is the date of the sample collection. | Data collection for this field is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise, leave blank.  
This field should be left blank if “Indication for Pap Test” (4.03) is ‘5’.  
This field should be left blank if “Indication for HPV Test” (4.10) is ‘3’. |
<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Column Begin</th>
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<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.13</td>
<td>Diagnostic Work-up Planned for Cervical Dysplasia or Cancer</td>
<td>1</td>
<td>107</td>
<td>107</td>
<td>1. Diagnostic work-up planned on basis of abnormal Pap test, HPV test or pelvic exam</td>
<td>If “Indication for Pap Test” (4.03) is ‘1’, ‘2’, ‘3’, ‘4’, ‘6’ or ‘9’ this field must be completed; otherwise, leave blank.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Diagnostic work-up not planned</td>
<td>If this field is coded as ‘1’, the Cervical Diagnosis Information Section must be completed. If this field is coded as ‘2’ or ‘3’, the Cervical Diagnosis Information Section must be blank.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. Diagnostic work-up plan not yet determined</td>
<td></td>
</tr>
</tbody>
</table>
# Section 5: Breast Screening Information

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Column Begin</th>
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<th>Codes / Format / Comments</th>
<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
</table>
| 5.01        | Indication for Initial Mammogram | 1             | 108          | 108        | 1. Screening  
2. Diagnostic  
3. Non-program mammogram, Referred in for diagnostic evaluation  
4. No mammogram  
5. No Breast Service  
9. Unknown | If Indication for Initial Mammogram is ‘5’ then items 5.02 – 5.11 should be blank.  
Data collection for this field is effective 01/01/2009, but no records should be blank. Historical data can be reported if accurately collected; otherwise, report a cycle with mammogram data as ‘9’ (Unknown). A cycle with cervical only data should be reported as ‘5’ (No Breast Service).  
‘1’ (Screening) should be reported for a mammogram performed as part of a routine or annual screening schedule and in the absence of symptoms or a recent positive CBE.  
‘2’ (Diagnostic) should be reported for a mammogram performed as additional evaluation of a recent mammogram prior to this cycle, evaluation of current symptoms or abnormal CBE finding, or prior history of breast cancer.  
‘3’ (Referred) should be reported when a patient has had a mammogram performed outside of the Program, and is referred to the Program for diagnostic work-up. Referral Date (5.03) must be completed, and a valid Mammogram Result (5.07) of ‘1’ – ‘5’, ‘7’, ‘11’, or ‘14’ – ‘15’ should be reported.  
‘4’ (No Mam) should be reported when the patient only received a CBE or screening MRI; or when the patient does not have an initial mammogram performed and goes directly to Diagnostic Work-up. Items 5.07 – 5.08 should be blank.  
‘5’ (No Breast Service) should be reported when no breast services are provided or reported in this record, only cervical services. Items 5.02 – 5.11 should be blank. |
<table>
<thead>
<tr>
<th>Item Number</th>
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</tr>
</thead>
</table>
| 5.02        | Breast Service Paid by NBCCEDP Funds [PN Abbreviated Field] | 1             | 109          | 109       | 1. Yes  
2. No  
3. Unknown | Data collection for this field is effective 01/01/2019. Historical data can be reported if accurately collected; otherwise, code as ‘3’ (Unknown).  
This field should be left blank if “Indication for Mammogram” (5.01) is ‘5’.  
If Mammogram, CBE, MRI or at least one breast imaging or diagnostic procedures was paid by NBCCEDP Funds, then this field should be set to ‘1’ (Yes). |
| 5.03        | Breast Diagnostic Referral Date | 8             | 110          | 117       | If “Indication for Initial Mammogram” (5.01) = ‘3’, enter MMDDYYYY.  
If “Indication for Initial Mammogram” (5.01) = ‘4’ then 5.03 MAY be completed as MMDDYYYY; otherwise leave blank. | Data collection for this field is effective 01/01/2009. Historical data can be reported if accurately collected; otherwise, leave blank. |
| 5.04        | High Risk for Breast Cancer | 1             | 118          | 118       | 1. Yes  
2. No  
9. Not Assessed/Unknown | Data collection for this field is effective 01/01/2019. Historical data should be coded as ‘9’ (Unknown).  
This field should be left blank if “Indication for Mammogram” (5.01) is ‘5’.  
‘1’ (Yes) should be reported if risk was assessed and determined to be high risk as defined as a woman with BRCA mutation, a first-degree relative who is a BRCA carrier, a lifetime risk of 20-25% or greater as defined by risk assessment models, radiation treatment to the chest between ages 10-30, or personal or family history of genetic syndromes like Li-Fraumeni syndrome.  
‘2’ (No) should be reported if risk was assessed and not determined to be high risk  
‘9’ (Not Assessed/Unknown) should be reported if risk was not assessed, family history was not taken, genetic testing was not done or if risk is unknown. |
<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
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<th>Codes / Format / Comments</th>
<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
</table>
| 5.05        | Screening MRI results                      | 1             | 119          | 119        | 1. Negative (Category 1)  
2. Benign Finding (Category 2)  
3. Probably Benign indicated (Category 3)  
4. Suspicious (Category 4)  
5. Highly Suggestive of Malignancy (Category 5)  
6. Known Malignancy (Category 6)  
7. Incomplete — Need Additional Imaging Evaluation (Category 0)  
8. Results Pending  
9. Not done | Data collection for this field is effective 01/01/2019. Historical data should NOT be reported.  
This field should be left blank if “Indication for Mammogram” (5.01) is ‘5’ or “High Risk of Breast Cancer” (5.04) ≠ ‘1’. |
| 5.06        | Date of Screening MRI                      | 8             | 120          | 127        | If MRI Results (5.05) ≤ “7”, enter MMDDYYYY.  
If you know the date for ‘8’, enter MMDDYYYY, otherwise blank fill.  
If MRI Results (5.05) = “9” blank fill. | If not blank, must be a valid date.  
This field should be left blank if “Indication for Mammogram” (5.01) is ‘5’ or if “Screening MRI Results” (5.05) is ‘9’. |
| 5.07        | Initial Mammography Test Result            | 2             | 128          | 129        | 1. Negative (BI-RADS 1)  
2. Benign Finding (BI-RADS 2)  
4. Suspicious Abnormality - Biopsy should be considered (BI-RADS 4)  
5. Highly Suggestive of Malignancy - Appropriate action should be taken (BI-RADS 5)  
7. Unsatisfactory - This applies if the mammogram was technically unsatisfactory and could not be interpreted by radiologist.  
10. Result pending  
11. Result unknown, presumed abnormal, mammogram from non-program funded source  
14. Need evaluation or film comparison (BI-RADS 0)  
15. Known Biopsy-Proven Malignancy (BI-RADS 6)  
*Based on new BI-RADS guidance from the Fourth Edition 2003. (3) Probably Benign should not be reported as the initial mammogram result unless a complete work-up was performed prior to the screening cycle either within or outside of the program. Please refer to the Field Description in the Data User’s Manual for further details. | This field should be left blank if “Indication for Mammogram” (5.01) is ‘4’ or ‘5’.  
If the result of the initial mammogram is ‘4’, ‘5’, ‘11’ or ‘14’, the “Additional procedures needed to complete breast cycle” (5.11) should = ‘1’.  
A result of ‘7’ (Unsatisfactory) indicates that the cycle should be considered complete, and a new cycle will begin with the repeat mammogram.  
This variable should be the initial result of the first mammographic film only. If any additional imaging is needed, to obtain a final imaging result or if a film comparison is necessary to obtain a final imaging result, then report ‘14’.  
This field should = ‘11’ only when “Indication for Initial Mammogram” (5.01) is ‘4’ (Non-program mammogram, Referred in for diagnostic evaluation) and the actual result of the initial mammogram is not known. |

**Note:**
- MDE 7.0 Data User's Manual
- Revised August 2019
- Chapter 2 – Minimum Data Elements (MDEs)
## National Breast and Cervical Cancer Early Detection Program
### Minimum Data Elements (MDE) Data Definition Table

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</tr>
</thead>
<tbody>
<tr>
<td>5.08</td>
<td>Date of Initial Mammogram</td>
<td>8</td>
<td>130</td>
<td>137</td>
<td>If &quot;Initial Mammography Test Result&quot; ≤ '5', '7', '14', or '15' enter MMDDYYYY.</td>
<td>If not blank, must be a valid date.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If you know the date for '10' or '11', enter MMDDYYYY, otherwise blank fill.</td>
<td>This field should be left blank if &quot;Indication for Mammogram&quot; (5.01) is '4' or '5'.</td>
</tr>
<tr>
<td>5.09</td>
<td>Clinical Breast Exam</td>
<td>1</td>
<td>138</td>
<td>138</td>
<td>1. Normal/Benign findings – schedule for routine CBE in one year 2. Abnormality suspicious for cancer – diagnostic evaluation needed 5. Not performed</td>
<td>This field should be left blank if &quot;Indication for Mammogram&quot; (5.01) is '5'.</td>
</tr>
<tr>
<td>5.10</td>
<td>Date of Clinical Breast Exam</td>
<td>8</td>
<td>139</td>
<td>146</td>
<td>If &quot;Clinical Breast Exam&quot; = '1' or '2', enter MMDDYYYY  If &quot;Clinical Breast Exam&quot; = 5 blank fill.</td>
<td>This field should be left blank if &quot;Indication for Mammogram&quot; (5.01) is '5'.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If &quot;Clinical Breast Exam&quot; = '1' or '2', enter MMDDYYYY  If &quot;Clinical Breast Exam&quot; (5.09) = '1' or '2', enter MMDDYYYY  If &quot;Clinical Breast Exam&quot; (5.09) = '5', blank fill.</td>
<td></td>
</tr>
<tr>
<td>5.11</td>
<td>Additional Procedures Needed to Complete Breast Cycle</td>
<td>1</td>
<td>147</td>
<td>147</td>
<td>1. Additional procedures needed or planned. 2. Additional procedures not needed or planned. 3. Need or plan for additional procedures not yet determined</td>
<td>If &quot;Indication for Mammogram&quot; (5.01) is '1', '2', '3', '4' or '9' this field must be completed; otherwise, leave blank.  If this field is coded as ‘1’, the Breast Diagnosis Information Section must be completed.  If this field is coded as ‘2’ or ‘3’, the Breast Diagnosis Information Section must be blank.  If “Indication for Initial Mammogram” (5.01) is ‘3’, then this field must = ‘1’ (Additional procedures needed or planned) and the Breast Diagnosis Information Section must be completed.</td>
</tr>
<tr>
<td>5.12</td>
<td>MDE Version Number</td>
<td>2</td>
<td>148</td>
<td>149</td>
<td>Note that the period in the version number is not included. For example, version 7.0 will be submitted as ‘70’. Only certain records with historical CBE data should use ‘21’.</td>
<td></td>
</tr>
</tbody>
</table>

MDE Version Number:
- For all other data collected: 70.
### National Breast and Cervical Cancer Early Detection Program
Minimum Data Elements (MDE) Data Definition Table

#### Cervical Final Diagnosis and Treatment Sections:
These sections must be completed if Diagnostic Work-up Planned for Cervical Dysplasia or Cancer (4.13) = ‘1’ (planned), otherwise leave blank.

### Section 6: Cervical Final Diagnosis Information

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
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<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
</table>
| 6.01        | Status of Final Diagnosis| 1             | 150          | 150        | 1. Work-up complete  
2. Work-up pending  
3. Lost to follow-up  
4. Work-up refused  
9. Irreconcilable  
A response of “9” will be used for those records, which after clinical review; it was determined that there was no sufficient way to translate the clinical scenario into the MDE data record. An example would be: If the clinician refers the woman for short-term follow-up instead of following the guideline for immediate diagnostic work-up, enter a ‘9’ to indicate a closed cycle with an irreconcilable status. | Range check. |
| 6.02        | Final Diagnosis          | 1             | 151          | 151        | 1. Normal/Benign reaction/inflammation  
2. HPV/Condylomata/Atypia  
3. CIN1/mild dysplasia (biopsy diagnosis)  
4. CIN2/moderate dysplasia (biopsy diagnosis)  
5. CIN3/severe dysplasia/Carcinoma in situ (Stage 0) or Adenocarcinoma In Situ of the cervix (AIS) (biopsy diagnosis)  
6. Invasive Cervical Carcinoma (biopsy diagnosis)  
7. Other  
8. Low grade SIL (biopsy diagnosis)  
9. High grade SIL (biopsy diagnosis)  
Range check.  
Low grade SIL and High grade SIL are provided as alternatives to diagnoses 2-5 and only one diagnosis should be submitted.  
Invasive Adenocarcinoma of the cervix should be coded as a ‘6’ (Invasive Cervical Carcinoma). Adenocarcinoma In Situ (AIS) of the cervix should be coded as ‘5’ (CIN3/severe dysplasia/CIS/AIS). | Check the skip pattern. |
| 6.03        | Final Diagnosis – Other   | 20            | 152          | 171        | Free text format, Description of “Final Diagnosis - Other”. | Check the skip pattern. |
## National Breast and Cervical Cancer Early Detection Program
### Minimum Data Elements (MDE) Data Definition Table

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</tr>
</thead>
<tbody>
<tr>
<td>6.04</td>
<td>Date of Final Diagnosis</td>
<td>8</td>
<td>172</td>
<td>179</td>
<td>If Status of Final Diagnosis (6.01) = ‘1’ enter MMDDYYYY, the date of diagnosis of cancer or precancerous lesion or date the decision made that no cancer is present. If Status of Final Diagnosis (6.01) = ‘2’ then blank fill. If Status of Final Diagnosis (6.01) = ‘3’, ‘4’ or ‘9’ then enter MMDDYYYY, the date of administrative closeout.</td>
<td>See edit guidelines for dates at the end of this document.</td>
</tr>
</tbody>
</table>

### Section 7: Cervical Cancer Treatment Information

This section is completed based on the results of MDE Item 6.02 (Final Diagnosis).

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
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<th>Column End</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
</table>
| 7.01        | Status of Treatment            | 1             | 180          | 180        | 1. Treatment started  
2. Treatment pending  
3. Lost to follow-up  
4. Treatment refused  
5. Treatment not needed | A woman should be classified as having started treatment when the Program has confirmed that a plan for treatment of the cancer or precancerous lesion has been developed and started. Range and skip pattern check. If Final Diagnosis (6.02) = ‘4’, ‘5’, ‘6’, or ‘9’ then complete 7.01 and 7.02. If Final Diagnosis (6.02) = ‘2’, ‘3’, ‘7’, or ‘8’ then 7.01 and 7.02 MAY be completed. If Final Diagnosis (6.02) = ‘1’, then 7.01 and 7.02 should be left blank. If a woman dies before treatment has started, enter a ‘3’ (Lost to follow-up). |
| 7.02        | Date of Treatment Status       | 8             | 181          | 188        | If Status of Treatment (7.01) = ‘1’ enter MMDDYYYY, the date that treatment of cancer or precancerous lesion began. If Status of Treatment (7.01) = ‘2’ then blank fill. If Status of Treatment (7.01) = ‘3’, ‘4’, or ‘5’ then enter MMDDYYYY, the date of administrative closeout. | Check the skip pattern. If not blank, should be ≥ “Date of Final Diagnosis” (6.04). |
### National Breast and Cervical Cancer Early Detection Program
### Minimum Data Elements (MDE) Data Definition Table

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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Breast Final Diagnosis and Treatment Sections:</strong> These sections must be completed if Additional Procedures Needed to Complete Breast Cycle (5.11) = ‘1’ (planned), otherwise leave blank.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Section 8: Breast Final Diagnosis Information</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 8.01        | Status of Final Diagnosis / Imaging    | 1             | 189          | 189        | 1. Work-up complete  
2. Work-up pending  
3. Lost to follow-up  
4. Work-up refused  
9. Irreconcilable  

A response of ‘9’ will be used for those records, which after clinical review, it was determined that there was no sufficient way to translate the clinical scenario into the MDE data record. An example would be: If the clinician refers the woman for short-term follow-up instead of following the guideline for immediate diagnostic work-up, enter a ‘9’ to indicate a closed cycle with an irreconcilable status. | Range check. |
| 8.02        | Final Diagnosis [PN Abbreviated Field] | 1             | 190          | 190        | 1. Carcinoma In Situ, Other*  
2. Invasive Breast Cancer  
3. Breast Cancer Not Diagnosed  
4. Lobular Carcinoma In Situ (LCIS) - (Stage 0)  
5. Ductal Carcinoma In Situ (DCIS) - (Stage 0)  

*Category (1) - CIS, Other is not a current reporting option for Final Diagnosis. It was used to report CIS diagnoses prior to 10/01/1999. | Range check. |
| 8.03        | Date of Final Diagnosis / Imaging      | 8             | 191          | 198        | If Status of Final Diagnosis/Imaging (8.01) = ‘1’, then enter MMDDYYYY, the date of diagnosis of cancer or date that decision made that no cancer is present.  
If Status of Final Diagnosis/Imaging (8.01) = ‘2’, then blank fill.  
If Status of Final Diagnosis/Imaging (8.01) = ‘3’, ‘4’ or ‘9’ then enter MMDDYYYY, the administrative date of closeout of this episode. | See edit guidelines for dates at the end of this document. |

The “Date of Final Diagnosis/Imaging” (8.03) should be the date of the definitive procedure indicating cancer or not cancer.
<table>
<thead>
<tr>
<th>Item Number</th>
<th>Variable Name</th>
<th>Column Length</th>
<th>Column Begin</th>
<th>Column End</th>
<th>Codes / Format / Comments</th>
<th>Edit Checks/Skip Patterns</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.01</td>
<td>Status of Treatment</td>
<td>1</td>
<td>199</td>
<td>199</td>
<td>1. Treatment started</td>
<td>Range and skip pattern check.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Treatment pending</td>
<td>A woman should be classified as having started treatment when the Program has confirmed that a plan for treatment of the cancer or precancerous lesion has been developed and started.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3. Lost to follow-up</td>
<td>If Final Diagnosis (8.02) = ‘1’, ‘2’ or ‘5’ then complete 9.01 and 9.02.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4. Treatment refused</td>
<td>If Final Diagnosis (8.02) = ‘4’, then 9.01 and 9.02 MAY be completed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5. Treatment not needed</td>
<td>If Final Diagnosis (8.02) = ‘3’, then 9.01 and 9.02 should be blank.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If a woman dies before treatment has started, enter a ‘3’ (Lost to follow-up).</td>
<td></td>
</tr>
<tr>
<td>9.02</td>
<td>Date of Treatment</td>
<td>8</td>
<td>200</td>
<td>207</td>
<td>If Status of Treatment (9.01) = ‘1’, then enter MMDDYYYY, the date that treatment for cancer began.</td>
<td>Check the skip pattern. If not blank, should be ≥ “Date of Final Diagnosis” (8.03).</td>
</tr>
<tr>
<td></td>
<td>Status</td>
<td></td>
<td></td>
<td></td>
<td>If Status of Treatment (9.01) = ‘2’, then blank fill.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If Status of Treatment (9.01) = ‘3’, ‘4’, or ‘5’ then enter MMDDYYYY, the date of administrative closeout.</td>
<td></td>
</tr>
</tbody>
</table>

**Section 9: Breast Cancer Treatment Information** – This section is completed based on the results of Final Diagnosis (8.02).
### Cervical and Breast Cancer Registry Data Sections

Section 10: Cervical Cancer Registry Data – If Final Diagnosis (6.02) is a ‘6’ (Invasive Cervical Carcinoma) and the patient was screened as of January 1, 2004, then this section must be completed. This section is reserved for data acquired through a State Central Cancer Registry or an equivalent data source approved by CDC/IMS.

NAACCR Record Data Standards and Data Dictionary are available at [www.naaccr.org](http://www.naaccr.org).

<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| 10.01       | Registry Linkage Status              | 1             | 208          | 208        | 1. Linkage process pending  
2. Linkage process complete, record matched  
3. Linkage process attempted, record not matched | Range check. |
| 10.02       | Registry Date of Diagnosis           | 8             | 209          | 216        | MMDDYYYY                                                                                   | Leave blank if 10.01 = 1, 3.  
If not blank, must be a valid date. |
| 10.03       | Registry Summary Stage                | 1             | 217          | 217        | 0. In situ (IS)  
1. Localized (L)  
2. Regional, direct extension only (RE)  
3. Regional, regional lymph nodes only (RN)  
4. Regional, extension and nodes (RE+RN)  
5. Regional, NOS (RNOS)  
7. Distant (D)  
8. Not Applicable (NA)  
Leave blank if 10.01 = 1, 3.  
Note: These NAACCR data items are specific to definitions in place for the calendar year of the Registry Date of Diagnosis (10.02). |
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>10.04</td>
<td>Registry Collaborative Stage (CS) – Derived AJCC Stage Group</td>
<td>2</td>
<td>218</td>
<td>219</td>
<td><strong>Right Justify With Leading Zeroes</strong>&lt;br&gt;Range: 00-99</td>
<td>Leave blank if 10.01 = 1, 3.&lt;br&gt;Complete only if Registry Date of Diagnosis (10.02) = 01/01/2004 – 12/31/2015; otherwise leave blank.&lt;br&gt;Complete CS-Derived AJCC Stage Group 6th Edition as available since not required by NPCR registries.&lt;br&gt;While CS-Derived AJCC Stage Group expanded from 2-digits in the 6th Edition to 3-digits in the 7th Edition, the CDC does not plan to expand to 3-digits in the MDEs at this time. When reporting AJCC 7th, edition cases from 2010 forward, the MDEs will collect the first 2-digits of the 3-digit code which provide a general classification. Programs are encouraged to consult with their IT staff/system vendor and their Cancer Registry to assess the feasibility and need to expand this field to 3-digits in their database system. Programs are advised to truncate the 3-digit value when creating the MDE file by reporting the first two digits and dropping the last of the three digits.</td>
</tr>
</tbody>
</table>
National Breast and Cervical Cancer Early Detection Program
Minimum Data Elements (MDE) Data Definition Table

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</tr>
</thead>
</table>
| 11.01       | Registry Linkage Status | 1 | 220 | 220 | 1. Pending linkage  
2. Linked, matched  
3. Linked, not matched | Range check. |
| 11.02       | Registry Date of Diagnosis | 8 | 221 | 228 | MMDDYYYY | Leave blank if 11.01 = 1, 3. |
|             |              |               |              |            |                           | If not blank, must be a valid date. |
| 11.03       | Registry Summary Stage | 1 | 229 | 229 | 0. In situ (IS)  
1. Localized (L)  
2. Regional, direct extension only (RE)  
3. Regional, regional lymph nodes only (RN)  
4. Regional, extension and nodes (RE+RN)  
5. Regional, NOS (RNOS)  
7. Distant (D)  
8. Not Applicable (NA)  
|             |              |               |              |            |                           | Leave blank if 11.01 = 1, 3. |

Note: These NAACCR data items are specific to definitions in place for the calendar year of the Registry Date of Diagnosis (11.02).

Section 11: Breast Cancer Registry Data – If Final Diagnosis (8.02) is a ‘1’ (Carcinoma In Situ, Other), ‘2’ (Invasive Breast Cancer), ‘4’ (Lobular Carcinoma In Situ) or ‘5’ (Ductal Carcinoma In Situ) and the patient was screened as of January 1, 2004, then this section must be completed. This section is reserved for data acquired through a State Central Cancer Registry or an equivalent data source approved by CDC/IMS.

NAACCR Record Data Standards and Data Dictionary are available at [www.naaccr.org](http://www.naaccr.org).
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### Minimum Data Elements (MDE) Data Definition Table

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<tr>
<td>11.04</td>
<td>Registry Collaborative Stage (CS) – Derived AJCC Stage Group</td>
<td>2</td>
<td>230</td>
<td>231</td>
<td>Right Justify With Leading Zeroes</td>
<td>Leave blank if 11.01 = 1, 3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Complete only if Registry Date of Diagnosis (11.02) = 01/01/2004 – 12/31/2015; otherwise leave blank.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>Complete CS-Derived AJCC Stage Group 6th Edition as available since not required by NPCR registries.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td>While CS-Derived AJCC Stage Group expanded from 2-digits in the 6th Edition to 3-digits in the 7th Edition, the CDC does not plan to expand to 3-digits in the MDEs at this time. When reporting AJCC 7th edition cases from 2010 forward, the MDEs will collect the first 2-digits of the 3-digit code which provide a general classification. Programs are encouraged to consult with their IT staff/system vendor and their Cancer Registry to assess the feasibility and need to expand this field to 3-digits in their database system. Programs are advised to truncate the 3-digit value when creating the MDE file by reporting the first two digits and dropping the last of the three digits.</td>
</tr>
</tbody>
</table>

99. **End of Record Mark** – Completed for each MDE record

| End of Record/Newline | 1 | 232 | 232 | Character that ends the current record and begins a new line of text. | Example: Carriage Return-Line Feed |
General edit guidelines for:

**Dates:** If your data processing system does not store dates as complete dates (i.e. they are separate month, day, and year fields), you need to verify the individual fields. The month needs to be between 1 and 12 and the day, if specified, between 1 and 31 and appropriate for the month (i.e. no June 31). A common situation for some dates could be that the year is known, but the month or day is not. If this occurs, please blank fill only the unknown fields.

**Correct date sequences:** A correct sequence of dates that track screening, diagnosis, and treatment is very important. These relationships have been specified in the edit section above or in the Edits Application. Please check these date relationships to ensure that the date sequences are reasonable.

**Range checks:** These are performed on fields like Hispanic Origin (2.05), Race (2.06.x), etc. where specific values are requested. A simple check of these data before they are submitted will ensure that, for example, Hispanic Origin only has values of ‘1’ to ‘3’ as specified in the MDE documentation.

**Skip patterns:** There are fields in the MDEs that are supposed to be completed under certain circumstances and left blank in others. For example, Clinical Breast Exam Date (5.10) should only be completed if Clinical Breast Exam (5.09) is a ‘1’ or ‘2’. Thus please check to see that if, for example, 10 women have a ‘1’ or a ‘2’ for Clinical Breast Exam, that there are no more than 10 Clinical Breast Exam Dates (5.10).