



Case Definitions and Reporting Requirements for Pre-Invasive Cervical (C53) Lesions
For Cases Diagnosed ***in 2019 and later***

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The instructions in this document pertain to cases diagnosed in 2019 and later only. For cases diagnosed prior to 2019, please refer to the Case Definitions and Reporting Requirements for Pre-Invasive Cervical (C53) Lesions for Cases Diagnosed Prior to 2019.

The case definitions for pre-invasive cervical lesions (C53) are effective for cases diagnosed **in 2019 or later** are as follows:

Eligible Cases

The determination of whether a case is reportable to MCSP is based on the information included in the pathology report, particularly in the section describing the final diagnosis. Eligibility is limited to cases with histologically confirmed tissue biopsies; cases identified by only a cytology report are not eligible for inclusion.

Cases using the following histologic terms in the pathologic diagnosis are eligible for inclusion (reportable) and must be reported as applicable. If any of the following histologic terms are recorded on the pathology report, submit a complete case report within the format and timeframe as specified by MCSP, and include the final histologic diagnosis exactly as it appears on the pathology report, including applicable information recorded in the comment section, addendums and if performed immunostaining test type and results in the Pathology Text Field:

- AIS
- CIS
- CIN 3
- Severe Dysplasia
- HSIL, HGSIL or High-Grade Dysplasia with or without additional CIN 3 or CIN 2-3 or CIN 2/3 terms
- CIN 2 if positive for p16*
- CIN 2/3 or CIN 2-3 if positive for p16*

* For cases in which positive p16 staining is required, such testing must apply to biopsy specimen and cannot be based on cervical smear cytology results. Pertinent immunostaining and results must be recorded in Pathology Text Field. "Focal" is NOT considered positive for p16.

Note: In September of 2012, the Lower Anogenital Squamous Terminology [LAST] Project convened by the College of American Pathologists (CAP) and the American Society for Colposcopy and Cervical Pathology (ASCCP) adopted a two-tier terminology that incorporates ancillary tests and other criteria to distinguish indeterminate lesions as high grade (HSIL) and low grade (LSIL). **To separate lesions formerly diagnosed as CIN grade 2 into high-grade SILs (HSIL) and low-grade SILs (LSIL), the LAST group recommended the use p16 immunostaining to classify these lesions as LSIL or HSIL.** Based upon College of American Pathologists (CAP) guidelines, the immunohistochemistry (IHC) results (if performed) is to be recorded on the pathology report. **It is important to know** if the pathology department that reads the facility cervical tissue specimens has adopted the two-tier terminology, type of immunostaining performed (i.e. p16, ProEx C, Ki-67) to classify indeterminate lesions diagnosed as CIN grade 2 (CIN II) into LSIL or HSIL, and where and how the ICH test results are recorded (i.e. pathology report).

Below is a summary of the inclusion criteria for determination of an eligible case.

- Synonyms for in situ carcinoma may include:
 - CIN grade III

- Confined to epithelium
- Intraepidermal
- Intraepithelial
- Involvement up to but not including the basement membrane
- Noninfiltrating, noninvasive
- No stromal involvement
- Papillary noninfiltrating
- Other synonyms may include:
 - HSIL
 - HGSIL
 - High-grade SIL
 - High grade squamous intraepithelial neoplasia
 - High grade squamous dysplasia.
- For any case that comes in with a histology other than those listed, the pathology report should be carefully reviewed to make sure that it is not an invasive lesion (path report should specifically indicate “in situ” behavior) and that the histology has been coded accurately.
- Review the histologically confirmed diagnosis in its entirety to determine if any reportable conditions exist based on all reported terminology and staining and results included in the pathology report. If necessary, check with lab to locate immunostaining information in patient record.

Table 1: Eligibility/Inclusion Criteria

Site (ICD-O-3)	C53.0 (endocervix) C53.1 (exocervix) C53.8 (overlapping lesions of cervix uteri) C53.9 (cervix uteri)
Behavior	2 (in situ or non-invasive)
Squamous type histologies	8010/2 Carcinoma in situ, NOS 8050/2 Papillary carcinoma in situ 8052/2 Papillary squamous cell carcinoma, non-invasive 8070/2 Squamous cell carcinoma in situ, NOS 8071/2 Squamous cell carcinoma, keratinizing, NOS, in situ 8072/2 Squamous cell carcinoma, large cell, non-keratinizing, in situ 8076/2 Squamous cell carcinoma in situ with question(able) stromal invasion 8077/2 Squamous intraepithelial neoplasia grade III
Adenocarcinoma type histologies	8140/2 Adenocarcinoma in situ 8560/2 Adenosquamous carcinoma (cases with behavior code 2 only)
Pathologic Classification	CIN III, CIS, AIS, severe dysplasia, HSIL, CIN II if positive for p16, CIN II/III or CIN II-III if positive for p16

Ambiguous Terminology

The ambiguous terms used to determine reportable pre-invasive cervical lesions are different than those used with other primary sites. The following rules are to be used in the reporting of pre-invasive cervical (C53) lesions.

The following qualifiers in the pathology report can be considered diagnostic for histology:

- Consistent with
- At least
- Compatible with
- Focal (for histology, not for p16)

Example: If the pathology report says, “consistent with high grade squamous intraepithelial lesion,” this would count as HSIL.

The following qualifiers are non-diagnostic:

- Suggestive of
- Cannot exclude
- Suspicion of
- Highly suspicious for
- Possible
- Favors
- Bordering
- Concerning for
- Worrisome for
- Approaching
- _____ cannot be ruled out

Example: If the pathology report says, “cannot exclude HSIL,” this would NOT be counted as HSIL.

Use of the word “to” as a connector:

The word “to” between two different grades of histology indicates that the specific grades were not clearly observed, so the lowest grade should be reported.

Example: If the pathology report says, “moderate to severe dysplasia,” this would NOT be considered severe dysplasia.

Rule for p16 (immunohistochemistry)

- “Focal” is NOT considered positive for p16
- Information on p16 positivity should be from the current specimen. Information on p16 from prior biopsies should not be used.

Examples:

Spectrum of low grade to high grade squamous intraepithelial lesion (mild to moderate squamous dysplasia, CIN-1-CIN-2)

The “to” connector rule states that the lowest grade should be reported. However, in this case the lowest grade would be “low,” which is not an eligible term.

Case is NOT REPORTABLE

Low grade squamous intraepithelial lesion (LSIL, CIN1). Scant poorly oriented dysplastic epithelium, at least low grade squamous intraepithelial lesion (LSIL, CIN 1). Cannot exclude high grade squamous intraepithelial lesion (HSIL, CIN 2) - Benign endocervical mucosa.

“Cannot exclude” is non-diagnostic, so this case should NOT be counted as HSIL.

Case is NOT REPORTABLE.

Focal squamous dysplasia, NOS (See Comments). Comments: The focus of squamous dysplasia is present in a minute, detached tissue fragment (less than 0.3mm in greatest dimension). The vast majority (99%) of the biopsy consist of unremarkable squamous mucosa. The dysplastic fragment is tangentially oriented, precluding accurate grading. However, a high-grade dysplasia is favored.

The qualifier “favors” or “favored” is non-diagnostic, so this case should NOT be counted as high-grade dysplasia.

Case is NOT REPORTABLE.

CIN II report that has “focal overexpression” of p16.

“Focal” is not considered positive for p16, so this case should not be included.

Case is NOT REPORTABLE.

Other non-reportable examples:

- The term “CIN 2” alone without positive p16 staining is **not** reportable; however, the term “HSIL (CIN2)” is reportable with or without positive p16 staining.
- “CIN 2-3” without positive p16 staining is **not** reportable; however, the term “HSIL (CIN2-3)” is reportable with or without positive p16 staining.
- “CIN 2/3” without positive p16 staining is **not** reportable; however, the term “HSIL (CIN2/3)” is reportable with or without positive p 16 staining.
- “Moderate to severe dysplasia” alone is **not** reportable
- “CIN I” is **not** reportable
- “LSIL, Low grade intraepithelial lesion” is **not** reportable

Casefinding

- Case finding sources will include pathology laboratories—private, reference, and hospital.
- Case finding is to be performed by manual review of pathology reports or an electronic search using CIN related key words or phrases, ICD-9 CM codes or ICD-10-CM codes.
- The appropriate ICD-9-CM code is 233.1 (CIN III/CIS/Severe Dysplasia).
- The appropriate ICD-10-CM code is D06. __ (CIN III/CIS/Severe Dysplasia).
- A list of eligible SNOMED codes is included below (See Table 3.)

Table 2: MCSP Reportable Pre-Invasive Cervical (C53) Conditions

Reportable Conditions				
ICD-10-CM Code	ICD-9-CM Code	Diagnostic Description	Histology Code/Cell Behavior	Topography Code
D06. __	233.1	AIS (adenocarcinoma in situ)	8140/2	C53.0 - C53.9
D06. __	233.1	CIN III (cervical intraepithelial neoplasia, grade 3)	8077/2	C53.0 - C53.9
D06. __	233.1	CIS (carcinoma in situ)	8070/2	C53.0 - C53.9
D06. __	233.1	“Severe dysplasia” alone is reportable in cases in which the pathologist uses neither CIN nor HSIL designations.	8077/2	C53.0 - C53.9
D06. __	233.1	HSIL or HGSIL (high-grade squamous intraepithelial lesion). Note that the terms “high grade squamous dysplasia,” “high grade squamous intraepithelial neoplasia,” and “high grade dysplasia” are now considered synonymous with “HSIL”.	8077/2	C53.0 - C53.9
D06. __	233.1	CIN II/III or CIN II-III only if positive for p16	8077/2	C53.0 - C53.9
D06. __	233.1	CIN II only if positive for p16	8077/2	C53.0 - C53.9

Table 3: Eligible SNOMED codes for cases diagnosed 2019 and later.

Histology	SNOMED Concept ID	SNOMED Legacy Code
Adenocarcinoma in situ	51642000	M-81402
Squamous Cell Carcinoma in situ	59529006	M-80702
Squamous Intraepithelial Neoplasia Grade III	20365006	M-80772
High-Grade Squamous Intraepithelial Lesion		M-67017

Timing and Histology Rules

The multiple primary and histology rules used to determine reportable pre-invasive cervical lesions are different than the Solid Tumor Rules used to make these determinations for other primary sites. The following rules are to be used in the reporting of pre-invasive C53 lesions. Histological confirmation is required in all cases; positive cytology alone is not sufficient.

The 12-month time period rule should be **applied separately** for in situ squamous type lesions and in situ adenocarcinoma type lesions as defined in Table 1. The diagnosis date of the first reported lesion

should be used to define the start of the first 12-month time period: for example, if the first reported lesion is diagnosed 3/15/2019, the first 12-month time period for determining ineligibility of subsequent lesions **from the same histology type** is 3/15/2019 – 3/15/2020.

If a lesion is described as having **both** in situ squamous and in situ adenocarcinoma histologies, then both lesions are eligible for inclusion as two separate records (each one with a different histology code). Both records will have the same diagnosis date.

If a patient has multiple lesions from both histology types (squamous and adenocarcinoma), then each histology type will have its own 12-month time period for determining ineligibility of subsequent lesions with a similar histology.

If a patient is diagnosed with another pre-invasive lesion **within** a twelve-month period following diagnosis of the first eligible lesion, the subsequent lesion is eligible for inclusion **only if its histology is different** from the first eligible lesion, i.e., squamous vs. adenocarcinoma histology types (see Table 1.)
If a patient is diagnosed with another pre-invasive lesion with the same histology after the twelve-month period following the first eligible lesion, the subsequent lesion is eligible for inclusion.

Invasive and pre-invasive lesions

If a patient has **both** an in situ and invasive diagnosis on the same date, or if the invasive diagnosis follows a previously included in situ diagnosis **within** a twelve-month time period, the in-situ diagnosis is no longer considered to be eligible.

If a patient is diagnosed with a pre-invasive lesion **within** a 12-month time period after having been diagnosed with an invasive lesion, then the pre-invasive lesion is not considered to be eligible for inclusion.

Definitive Treatments for Pre-Invasive Cervical Lesions

For pre-invasive cervical (C53) lesions, code Local Tumor Excision, Excisional Biopsy, Dilation and Curettage, Cone Biopsy with gross excision of lesion, LEEP and/or combinations of surgical procedures as defined in 2018 STORE Manual: Appendix B: Site-Specific Surgery Codes as first course of treatment.

Note that LEEP procedure is considered most definitive surgical treatment for pre-invasive cervical lesions.

Example:

First course of treatment for a non-invasive cancer is documented as LEEP.

Code the RX Summ--Surgery Primary Site as 28.

Code an excision biopsy, even when documented as incisional, when:

- All disease is removed (margins free) OR
- All gross disease is removed and there is only microscopic residual at the margin
- Do NOT code an excision biopsy when there is macroscopic residual disease

All other treatment modalities such as Radiation, Chemotherapy, Hormone, or BRM would be coded to 00 - None.

Submission of Pre-Invasive Cervical Cancer Case Reports

These pre-invasive cervical lesions are not “reportable by agreement;” they are considered reportable conditions based upon Michigan compiled laws and [Administrative Rules on Cancer Reporting](#). A copy of the Administrative Rules is also available on the MCSP website at www.michigan.gov/mcsp

1. A complete NAACCR abstract (electronic submission) or a MI Cancer Report Form (manual submission) is required
2. TEXT is a required data item.
3. Record the histologically confirmed diagnosis in its entirety, exactly as it appears in the final diagnosis of the pathology report in Pathology Text Field. If multiple terms are used, include all of them. If immunostaining was performed, the test type (i.e. p16) is to be recorded.

Examples:

“High grade squamous intraepithelial lesion (severe dysplasia/CIN III)”

“HGSIL (severe dysplasia/squamous cell carcinoma in situ)”

4. Record all pertinent data regarding staining information in the Pathology Text Field including name of test and results.

If immunostaining is performed (i.e. p16, Ki-67 or ProEx C) is performed, record the name of the test and the results in the Pathology Text Field. If necessary, check with lab to locate immunostaining information if conducted in order to separate lesion formerly diagnosed as CIN grade 2 (CIN II) into high-grade SILs (HSIL) and low-grade SILs (LSIL).

Examples:

“High grade squamous intraepithelial lesion confirmed by positive p16 immunostain”

“Endocervical adenocarcinoma in situ (AIS). Cells are immunoreactive for P16 with a high Ki-67 proliferative index”

Electronic Submission of Data

1. Facilities who report cancer case reports to MCSP through Web Plus, must submit their data in the NAACCR format version specified by MCSP.
2. Electronic submission files through Web Plus must be free of edit errors.
3. In order to avoid data submission backlogs, facilities are requested to submit completed abstracts on a monthly basis.
4. **All reportable pre-invasive cervical lesions (C53) are required to be reported to MCSP within 90 days from the date of initial diagnosis.**
5. All other reportable conditions must be submitted within 180 days from the date of initial diagnosis, with monthly submission of data required.
6. If complete casefinding is conducted for a specific month/diagnosis year and no eligible cases were identified, please remit email confirmation of no eligible cases were identified during casefinding for month/diagnosis year to KosterD@michigan.gov and AlversonG@michigan.gov

Manual Submission of Data

1. Complete copy of MI Cancer Report Form for each separate reportable condition.
2. Use the most currently available copy of the form.
3. Form is available on MCSP web page at <http://www.michigan.gov/MCSP>
4. Include copies of all pertinent documents/reports that pertain to the patient diagnosis and/or first course of treatment with submitted form.
5. Examples of pertinent documents include: History and Physical Examination Report, Discharge Summary, Attestation Statement, Operative Report, Pathology Report, X-rays/Scans, Laboratory Reports, Consultation Report, Treatment Summary.
6. For more information, including submission of forms, refer to the MCSP Cancer Program Manual and applicable reference documents such as the stand-alone Case Definitions and Reporting Requirements for Pre-Invasive Cervical Lesions (C53) by diagnosis year (Prior to 2019, 2019 or Later), which are available at www.michigan.gov/mcsp

Contact Information

If you have questions regarding MI cancer reporting requirements for pre-invasive cervical (C53) , please email MCSP Field Representative, Doug Koster at KosterD@michigan.gov and cc Georgetta (Jetty) Alverson, Manager at AlversonG@Michigan.gov. If you are requesting case review for eligibility, please include the final diagnosis as it appears on the pathology report, comments, and applicable addendum(s), and include any questions you have in regard to case eligibility. Do not include any patient personal identifiers in the email.

Note: Tri-County Area (Wayne, Oakland, and Macomb)

If your registry submits cancer case reports to the Metropolitan Detroit Cancer Surveillance System (MDCSS) who submits data to MCSP, and you have questions regarding MI Cancer Reporting Requirements for pre-invasive cervical (C53) lesions, please contact Jeanne Whitlock at 313-578-4219 or whitlock@karmanos.org

MCSP strives to provide facilities with accurate and up-to-date cancer case reporting requirements. The role of MCSP is to collect and organize data, but the building blocks for the Michigan central cancer registry come from the reporting institutions who identify and submit the cases. Thank you for your continued cooperation in submitting timely, accurate and complete data to the MCSP.