Proposed Changes to Gender Documentation and Inclusion in Breast and Cervical Cancer Screening for HEDIS®[1] MY 2024

NCQA seeks comments on expanding the denominator populations of the *Breast Cancer Screening* and *Cervical Cancer Screening* measures to include transgender and gender-diverse members recommended for routine breast and cervical cancer screening. The proposed changes are summarized in Table 1.

Table 1: Proposed Measure Revisions

Measure	Current Measure Description	Revised Measure Description
Breast Cancer Screening	The percentage of women 50–74 years of age who had a mammogram to screen for breast cancer.	The percentage of members 50–74 years of age who were recommended for routine breast cancer screening and had a mammogram to screen for breast cancer.
Cervical Cancer Screening	The percentage of women members 21–64 years of age who were screened for cervical cancer.	The percentage of members 21–64 years of age who were recommended for routine cervical cancer screening and were screened for cervical cancer.

The denominator populations for these measures are currently defined as "women" and reference the member's gender on record with their health plan. Members whose gender is not listed with their plan as "woman" are excluded, even if their clinical traits warrant the screenings. This may contribute to existing disparities in care: evidence suggests rates of breast and cervical cancer screening for transgender and gender-diverse patients are lower than cisgender patient rates,[1] which can lead to more advanced disease at diagnosis.

The revised language is designed to better reflect the measures' intent, which is that all members who are recommended for routine breast and cervical cancer screening receive the screening. To identify the population of members recommended for routine screening, it is necessary to leverage more precise data elements that can be used to identify these populations in health plan data.

Screening Guidelines

Clinical practice guidelines recommend breast cancer screening for cisgender women,[2] transgender men[3] and gender-diverse patients assigned female at birth,[4] or with breasts from natal puberty,[5] who have not undergone bilateral mastectomy or gender-affirming chest reconstruction. Some guidelines also recommend breast cancer screening for transgender and gender-diverse patients assigned male at birth who have at least 5–10 years of gender-affirming estrogen therapy,[3,4] noting evidence to suggest that breast cancer risk is higher for this population than for cisgender men (although risk may still be lower than that of cisgender women).

Guidelines recommend cervical cancer screening for all patients with a cervix, [3,4,5,6,7] excluding patients who have undergone total hysterectomy.

[1]HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).

Data Standards to Identify Individuals Recommended for Routine Screening

Several data standards support documentation and exchange of patient sex and gender data. "Gender" refers to concepts representing a patient's identity, sense of self and expression; gender-related data are critical to providing affirming and patient-centered care.[8] "Sex" refers to concepts representing the categorizations (typically male, female) assigned to patients based on physiological traits. Sex-related data can be clinically useful in understanding someone's care needs, and are likely to be the most feasible method of identifying members who are recommended for routine breast and cervical cancer screening. Sex-related data elements recommended in the data standards (described in detail in the attached evidence workup) include Sex Assigned at Birth[9] and Sex for Clinical Use,[10] which refer to sex categorizations made based on clinical observations.

Anatomical inventories[11] are a recommended method of identifying patients who need routine breast and cervical cancer screening, but they are not widely implemented or reflected in data standards. Absent an anatomical inventory, Sex Assigned at Birth and Sex for Clinical Use may be clinically useful in approximating a patient's routine screening needs. Relative to the current specifications, these data elements are a more precise way of identifying members who need breast and cervical cancer screening. NCQA proposes to add these data elements to the denominator specifications for breast and cervical cancer screening.

Proposed Revisions

Breast Cancer Screening will assess screening among a denominator population of members recommended for routine breast cancer screening, including members with any of the following:

- Administrative gender of female *(currently in specification),* or
- Sex of "female" assigned at birth, or
- Sex for clinical use of "female" or "specified", or
- Administrative gender, sex assigned at birth or sex for clinical use of "male" ***and*** 5+ years of exposure to gender-affirming estrogen therapy.

The measure will exclude members with bilateral mastectomy, including gender-affirming chest reconstruction.

Cervical Cancer Screening will assess screening among members recommended for routine cervical cancer screening, including members with any of the following:

- Administrative gender of female *(currently in specification),* or
- Sex of "female" assigned at birth, ***or***
- Sex for clinical use of "female" or "specified.".

The measure will exclude members with total hysterectomy or acquired absence of cervix.

These revised denominator definitions better align with the measures' intent of identifying members who are recommended for these routine screenings, and may result in greater inclusion of gender diverse and intersex members. NCQA emphasizes that while the sex-related data elements used to specify these revised denominator populations represent more precise methods of identifying clinical screening needs, these data should never be collected absent parallel collection of gender identity or used to assume a patient's gender.

NCQA seeks feedback on the following questions:

1. Do you support the proposed denominator revisions for Breast Cancer Screening? What if any concerns do you have about the addition of *Sex Assigned at Birth* and *Sex for Clinical Use?*
    a. Do you support the inclusion of transgender and gender-diverse members with 5+ years of exposure to gender-affirming estrogen therapy? Should the required duration of estrogen exposure be lengthened to 10+ years?
2. Do you support the proposed denominator revisions for Cervical Cancer Screening? What if any concerns do you have about the addition of *Sex Assigned at Birth* and *Sex for Clinical Use?*

Supporting documents include draft measure specifications and an evidence workup.

NCQA acknowledges the contributions of the Breast Cancer Screening, Cervical Cancer Screening and Technical Measurement Advisory Panels and of the Health Equity Expert Work Group and the community organizations that provided input on this work.

[1] Oladeru, O.T., S.J. Ma, J.A. Miccio, K. Wang, K. Attwood, A.K. Singh, D.A. Haas-Kogan, and P.M. Neira. 2022. "Breast and Cervical Cancer Screening Disparities in Transgender People." *American Journal of Clinical Oncology* 45 (3): 116. https://doi.org/10.1097/COC.0000000000000893

[2] Siu, A.L. and U.S. Preventive Services Task Force (USPSTF). 2016. "Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement." *Annals of Internal Medicine* 164 (4): 279–96. https://doi.org/10.7326/M15-2886

[3] University of California San Francisco (UCSF) Center of Excellence for Transgender Health. 2016. *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People.* https://transcare.ucsf.edu/guidelines

[4] Fenway Health. 2021. *Medical Care of Trans and Gender Diverse Adults.* https://fenwayhealth.org/wp-content/uploads/Medical-Care-of-Trans-and-Gender-Diverse-Adults-Spring-2021-1.pdf

[5] Coleman, E., A.E. Radix, W.P. Bouman, G.R. Brown, A.L.C. de Vries, M.B. Deutsch, R. Ettner, et al. 2022. "Standards of Care for the Health of Transgender and Gender Diverse People, Version 8." *International Journal of Transgender Health* 23 (Suppl 1): S1–259. https://doi.org/10.1080/26895269.2022.2100644

[6] Fontham, Elizabeth T. H., Andrew M. D. Wolf, Timothy R. Church, Ruth Etzioni, Christopher R. Flowers, Abbe Herzig, Carmen E. Guerra, et al. 2020. "Cervical Cancer Screening for Individuals at Average Risk: 2020 Guideline Update from the American Cancer Society." *CA: A Cancer Journal for Clinicians* 70 (5): 321–46. https://doi.org/10.3322/caac.21628.

[7] US Preventive Services Task Force, S.J. Curry, A.H. Krist, D.K. Owens, M.J. Barry, A.B. Caughey, K.W. Davidson, et al. 2018. "Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement." *JAMA* 320 (7): 674. https://doi.org/10.1001/jama.2018.10897

[8] National Academies of Sciences, Engineering, and Medicine; Division of Behavioral and Social Sciences and Education; Committee on National Statistics; Committee on Measuring Sex, Gender Identity, and Sexual Orientation. *Measuring Sex, Gender Identity, and Sexual Orientation.* Edited by Tara Becker, Nancy Bates, and Marshall Chin. National Academies Press, March 9, 2022. https://doi.org/10.17226/26424

[9] Office of the National Coordinator for Health IT. *USCDI V1 Patient Demographics/Information.* https://www.healthit.gov/isa/taxonomy/term/731/uscdi-v1

[10] McClure, R.C, C.L Macumber, C. Kronk, C. Grasso, R.J. Horn, R. Queen, S. Posnack, and K. Davison. 2021. "Gender Harmony: Improved Standards to Support Affirmative Care of Gender-Marginalized People through Inclusive Gender and Sex Representation." *Journal of the American Medical Informatics Association* 29, no. 2: 354–63. https://doi.org/10.1093/jamia/ocab196

[11] Grasso, C., H. Goldhammer, J. Thompson, and A.S. Keuroghlian. 2021. "Optimizing Gender-Affirming Medical Care Through Anatomical Inventories, Clinical Decision Support, and Population Health Management in Electronic Health Record Systems." *Journal of the American Medical Informatics Association: JAMIA* 28(11), 2531–35. https://doi.org/10.1093/jamia/ocab080

Measure title	Breast Cancer Screening	**Measure ID**	BCS-E
Description	The percentage of ~~women~~ members 50–74 years of age who were recommended for routine breast cancer screening ~~who~~ and had a mammogram to screen for breast cancer.		
Measurement period	January 1–December 31.		
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Clinical recommendation statement	The U.S. Preventive Services Task Force recommends screening women 50–74 years of age for breast cancer every 2 years. (B recommendation) The Fenway Institute recommends that for patients assigned female at birth who have not undergone chest reconstruction (including those who have had breast reduction), breast/chest screening recommendations are the same as for cisgender women of a similar age and medical history. For transgender and gender-diverse patients on estrogen, the Fenway Institute recommends considering initial screening mammography starting at age 50, and only after they have been on estrogen therapy for more than 5 years. Thereafter, mammograms are recommended every 2 years, following screening guidelines for cisgender women. The University of California San Francisco Center for Transgender Health recommends that screening mammography be performed every 2 years for transgender women, once at age 50 and after 5–10 years of feminizing hormone use criteria have been met.
Citations	Fenway Health. (2021). *Medical Care of Trans and Gender Diverse Adults.* https://fenwayhealth.org/wp-content/uploads/Medical-Care-of-Trans-and-Gender-Diverse-Adults-Spring-2021-1.pdf University of California San Francisco Center of Excellence for Transgender Health. (2016). *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People.* https://transcare.ucsf.edu/sites/transcare.ucsf.edu/files/Transgender-PGACG-6-17-16.pdf U.S. Preventive Services Task Force. 2016. "Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med* 164(4):279–96.
Characteristics	
Scoring	Proportion.
Type	Process.
Stratification	• Breast Cancer Screening. – Product line: ▪ Commercial. ▪ Medicaid. ▪ Medicare. – SES (for Medicare only): ▪ SES – Non-LIS/DE, Nondisability. ▪ SES – LIS/DE. ▪ SES – Disability. ▪ SES – LIS/DE and Disability. ▪ SES – Other. ▪ SES – Unknown. – Race (for each product line): ▪ Race – White. ▪ Race – Black or African American.

	▪ Race – American Indian or Alaska Native. ▪ Race – Asian. ▪ Race – Native Hawaiian or Other Pacific Islander. ▪ Race – Some Other Race. ▪ Race – Two or More Races. ▪ Race – Asked but No Answer. ▪ Race – Unknown. – Ethnicity (for each product line): ▪ Ethnicity – Hispanic or Latino. ▪ Ethnicity – Not Hispanic or Latino. ▪ Ethnicity – Asked but No Answer. ▪ Ethnicity – Unknown.
Risk adjustment	None.
Improvement notation	A higher rate indicates better performance.
Guidance	For Medicare plans, I-SNP and LTI exclusions are not included in the measure calculation logic and must be programmed manually. **Allocation:** The member was enrolled with a medical benefit throughout the participation period. No more than one gap in enrollment of up to 45 days for each full calendar year of the participation period (i.e., the measurement period and the year prior to the measurement period). No gaps in enrollment are allowed from October 1 two years prior to the measurement period through December 31 two years prior to the measurement period. The member must be enrolled on the last day of the measurement period. When identifying members in hospice, the requirements for identification of hospice members using the monthly membership detail data files are not included in the measure calculation logic and need to be programmed manually. **Reporting:** For Medicare plans, the SES stratifications are mutually exclusive. NCQA calculates a total rate for Medicare plans by adding all six Medicare stratifications. For all plans, the race and ethnicity stratifications are mutually exclusive and the sum of all categories in each stratification is the total population. SES and product line stratifications are not included in the measure calculation logic and need to be programmed manually. The race and ethnicity stratifications are reported by data source (direct or indirect). The RES data source logic is not included in the measure calculation logic and must be programmed manually.

Definitions

Participation

The identifiers and descriptors used to define members' eligibility for measure reporting. Allocation for reporting is based on eligibility during the participation period.

Participation period

October 1 two years prior to the measurement period through the end of the measurement period.

Members recommended for routine breast cancer screening

Members recommended for routine breast cancer screening include members with any of the following:

- Administrative Gender of Female (AdministrativeGender code Female) at any time in the member's history.
- Sex Assigned at Birth (LOINC code 76689-0) of Female (LOINC code LA3-6) at any time in the member's history.
- Sex for Clinical Use (LOINC code 99501-9) of Female or Specified during the measurement period.
- Administrative Gender of Male (AdministrativeGender code Male) at any time in the member's history. Sex Assigned at Birth (LOINC code 76689-0) of Male (LOINC code LA2-8) at any time in the member's history, or Sex for Clinical Use (LOINC code 99501-9) of Male during the measurement period ***and*** ≥5 years exposure to gender-affirming estrogen therapy (Estrogen Medications List) as of the end of the measurement period. To calculate years of exposure, identify members with at least ~~1~~one dispensing event every year from 6 years prior to the start of the measurement period through the end of the measurement period:
  - Year 1: January 1—December 31st six~~6~~ years prior to the start of the measurement period.
  - Year 2: January 1—December 31st five~~5~~ years prior to the start of the measurement period.
  - Year 3: January 1—December 31st four~~4~~ years prior to the start of the measurement period.
  - Year 4: January 1—December 31st three~~3~~ years prior to the start of the measurement period.
  - Year 5: January 1—December 31st two~~2~~ years prior to the start of the measurement period.
  - Year 6: January 1—December 31st one~~1~~ year prior to the start of the measurement period.
  - Year 7: January 1—December 31st of the measurement period.

Estrogen Medications

Drug Class	Prescription	Medication List
Estrogens; include oral, transdermal and injectable products	• Conjugated estrogen • Esterified estrogen • Estradiol	Estrogen Medications List

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<tr><td>Initial population</td><td>~~Women~~ Members 52–74 years of age by the end of the measurement period who were recommended for routine breast cancer screening ~~who~~ and also meet the criteria for participation.</td></tr>
<tr><td>Exclusions</td><td>

Members who use hospice services (Hospice Encounter Value Set; Hospice Intervention Value Set) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these members must use only the run date of the file to determine if the member elected to use a hospice benefit during the measurement period.
Members who die any time during the measurement period.
Members who had a bilateral mastectomy or both right and left unilateral mastectomies any time during the member's history through the end of the measurement period. Any of the following meet the criteria for bilateral mastectomy:

Bilateral mastectomy (Bilateral Mastectomy Value Set).
Unilateral mastectomy (Unilateral Mastectomy Value Set) with a bilateral modifier (Bilateral Modifier Value Set) (same procedure).
Unilateral mastectomy found in clinical data (Clinical Unilateral Mastectomy Value Set) with a bilateral modifier (Clinical Bilateral Modifier Value Set) (same procedure).

Note: The "clinical" mastectomy value sets identify mastectomy; the word "clinical" refers to the data source, not to the type of mastectomy.
History of bilateral mastectomy (History of Bilateral Mastectomy Value Set).
Any combination of codes from the table below that indicate a mastectomy on both the left and right side on the same date of service or on different dates of service.
<table>
<tr><th>Left Mastectomy
(any of the following)</th><th>Right Mastectomy
(any of the following)</th></tr>
<tr><td>Unilateral mastectomy (Unilateral Mastectomy Value Set) with a left-side modifier (Left Modifier Value Set) (same procedure)</td><td>Unilateral mastectomy (Unilateral Mastectomy Value Set) with a right-side modifier (Right Modifier Value Set) (same procedure)</td></tr>
<tr><td>Unilateral mastectomy found in clinical data (Clinical Unilateral Mastectomy Value Set) with a left-side modifier (Clinical Left Modifier Value Set) (same procedure)</td><td>Unilateral mastectomy found in clinical data (Clinical Unilateral Mastectomy Value Set) with a right-side modifier (Clinical Right Modifier Value Set) (same procedure)</td></tr>
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	<table><tr><td>Absence of the left breast (Absence of Left Breast Value Set)</td><td>Absence of the right breast (Absence of Right Breast Value Set)</td></tr><tr><td>Left unilateral mastectomy (Unilateral Mastectomy Left Value Set)</td><td>Right unilateral mastectomy (Unilateral Mastectomy Right Value Set)</td></tr></table> • Members who had gender-affirming chest surgery (CPT code 19318) with a diagnosis of Gender Dysphoria (Gender Dysphoria Value Set) any time during the member's history through the end of the measurement period. • Medicare members 66 years of age and older by the end of the measurement period who meet either of the following: – Enrolled in an Institutional SNP (I-SNP) any time during the measurement period. – Living long-term in an institution any time during the measurement period, as identified by the LTI flag in the monthly membership detail data file. Use the run date of the file to determine if a member had an LTI flag during the measurement period. • Members 66 years of age and older by the end of the measurement period, with frailty and advanced illness. Members must meet BOTH frailty and advanced illness criteria to be excluded: – **Frailty.** At least two indications of frailty (Frailty Device Value Set; Frailty Diagnosis Value Set; Frailty Encounter Value Set; Frailty Symptom Value Set) with different dates of service during the measurement period. Do not include laboratory claims (claims with POS 81). – **Advanced Illness.** Either of the following during the measurement period or the year prior to the measurement period: ▪ Advanced illness (Advanced Illness Value Set) on at least two different dates of service. Do not include laboratory claims (claims with POS 81). ▪ Dispensed dementia medication (Dementia Medications List). • Members receiving palliative care (Palliative Care Assessment Value Set; Palliative Care Encounter Value Set; Palliative Care Intervention Value Set) any time during the measurement period. • Members who had an encounter for palliative care (ICD-10-CM code Z51.5) any time during the measurement year. Do not include laboratory claims (claims with POS 81).
Denominator	The initial population, minus exclusions.
Numerator	One or more mammograms (Mammography Value Set) any time on or between October 1 two years prior to the measurement period and the end of the measurement period.
Data criteria (element level)	
Value sets: • BCSE_HEDIS_MY2023-2.0.0 – Absence of Left Breast (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1329)	

  - Absence of Right Breast (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1330)
  - Bilateral Mastectomy (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1042)
  - Bilateral Modifier (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1043)
  - Clinical Bilateral Modifier (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1951)
  - Clinical Left Modifier (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1949)
  - Clinical Right Modifier (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1950)
  - Clinical Unilateral Mastectomy (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1948)
  - History of Bilateral Mastectomy (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1331)
  - Left Modifier (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1148)
  - Mammography (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1168)
  - Right Modifier (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1230)
  - Unilateral Mastectomy (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1256)
  - Unilateral Mastectomy Left (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1334)
  - Unilateral Mastectomy Right (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1335)
- NCQA_AdvancedIllnessandFrailty-2.0.0
  - Acute Inpatient (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1810)
  - Advanced Illness (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1465)
  - Dementia Medications (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1729)
  - ED (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1086)
  - Frailty Device (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1530)
  - Frailty Diagnosis (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1531)
  - Frailty Encounter (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1532)
  - Frailty Symptom (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1533)
  - Nonacute Inpatient (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1189)
  - Observation (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1191)
  - Online Assessments (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1446)
  - Outpatient (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1202)
  - Telephone Visits (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1246)
- NCQA_Claims-2.0.0
  - Inpatient Stay (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1395)
  - Nonacute Inpatient Stay (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1398)
- NCQA_Hospice-2.0.0
  - Hospice Encounter (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1761)
  - Hospice Intervention (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1762)
- NCQA_PalliativeCare-2.0.0
  - Palliative Care Assessment (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2225)

  - Palliative Care Encounter (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1450)
  - Palliative Care Intervention (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2224)
- NCQA_Stratification-1.0.0
  - American Indian or Alaska Native Detailed Race (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2365)
  - Asian Detailed Race (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2366)
  - Black or African American Detailed Race (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2367)
  - Hispanic or Latino Detailed Ethnicity (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2368)
  - Native Hawaiian or Other Pacific Islander Detailed Race (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2369)
  - White Detailed Race (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2370)

Direct reference codes and codesystems:

- NCQA_PalliativeCare-2.0.0
  - codesystem "ICD-10-CM": 'http://hl7.org/fhir/sid/icd-10-cm'
  - code "Encounter for palliative care": 'Z51.5' from "ICD-10-CM" display 'Encounter for palliative care'
- NCQA_Terminology-2.0.0
  - codesystem "ActCode": 'http://terminology.hl7.org/CodeSystem/v3-ActCode'
  - codesystem "ClaimTypeCodes": 'http://terminology.hl7.org/CodeSystem/claim-type'
  - codesystem "ConditionClinicalStatusCodes": 'http://terminology.hl7.org/CodeSystem/condition-clinical'
  - codesystem "NullFlavor": 'http://terminology.hl7.org/CodeSystem/v3-NullFlavor'
  - codesystem "RaceAndEthnicityCDC": 'https://www.hl7.org/fhir/us/core/CodeSystem-cdcrec'
  - code "active": 'active' from "ConditionClinicalStatusCodes"
  - code "American Indian or Alaska Native": '1002-5' from "RaceAndEthnicityCDC" display 'American Indian or Alaska Native'
  - code "Asian": '2028-9' from "RaceAndEthnicityCDC" display 'Asian'
  - code "Asked but no answer": 'ASKU' from "NullFlavor" display 'Asked but no answer'
  - code "Black or African American": '2054-5' from "RaceAndEthnicityCDC" display 'Black or African American'
  - code "Hispanic or Latino": '2135-2' from "RaceAndEthnicityCDC" display 'Hispanic or Latino'
  - code "Institutional": 'institutional' from "ClaimTypeCodes"
  - code "managed care policy": 'MCPOL' from "ActCode"
  - code "Native Hawaiian or Other Pacific Islander": '2076-8' from "RaceAndEthnicityCDC" display 'Native Hawaiian or Other Pacific Islander'
  - code "Non Hispanic or Latino": '2186-5' from "RaceAndEthnicityCDC" display 'Non Hispanic or Latino'
  - code "Other": 'OTH' from "NullFlavor" display 'Other'
  - code "Pharmacy": 'pharmacy' from "ClaimTypeCodes"

- code "Professional": 'professional' from "ClaimTypeCodes"
- code "retiree health program": 'RETIRE' from "ActCode"
- code "subsidized health program": 'SUBSIDIZ' from "ActCode"
- code "Unknown": 'UNK' from "NullFlavor" display 'Unknown'
- code "White": '2106-3' from "RaceAndEthnicityCDC" display 'White'

Cervical Cancer Screening (CCS)

SUMMARY OF CHANGES TO HEDIS MY 2024

- Replaced references to "women" ~~to~~with "members recommended for routine cervical cancer screening."
- Added exclusion for members who were assigned male at birth.

Description

The percentage of ~~women~~ members 21–64 years of age who were recommended for routine cervical cancer screening and ~~who are and~~ ~~who who~~ were screened for cervical cancer using any of the following criteria:

- ~~Women~~ Members 21–64 years of age who were recommended for routine cervical cancer screening ~~who are~~ ~~who~~and~~who~~and had cervical cytology performed within the last 3 years.
- ~~Women~~ Members 30–64 years of age who were recommended for routine cervical cancer screening ~~who are who and who~~and had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years.
- ~~Women~~ Members 30–64 years of age who were recommended for routine cervical cancer screening ~~who are who~~and~~who~~and had cervical cytology/high-risk human papillomavirus (hrHPV) cotesting within the last 5 years.

Definitions

Members recommended for routine cervical cancer screening

Members recommended for routine cervical cancer screening include members with:

- Administrative Gender of Female (AdministrativeGender code Female) at any time in the member's history.
- Sex Assigned at Birth (LOINC code 76689-0) of Female (LOINC code LA3-6) at any time in the member's history.
- Sex for Clinical Use (LOINC code 99501-9) of Female or Specified during the measurement period.

Eligible Population

Product lines	Commercial, Medicaid (report each product line separately).
Ages	~~Women~~ Members 24–64 years who were recommended for routine cervical cancer screening as of December 31 of the measurement year.
Continuous enrollment	*Commercial:* The measurement year and the 2 years prior to the measurement year. *Medicaid:* The measurement year.

Allowable gap	No more than one gap in enrollment of up to 45 days during each year of continuous enrollment. To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, the member may not have more than a 1-month gap in coverage (e.g., a member whose coverage lapses for 2 months [60 days] is not considered continuously enrolled).
Anchor date	December 31 of the measurement year.
Benefit	Medical.
Event/diagnosis	None.
Required exclusions	Exclude members who meet any of the following criteria: • Hysterectomy with no residual cervix (Hysterectomy With No Residual Cervix Value Set) any time during the member's history through December 31 of the measurement year. • Cervical agenesis or acquired absence of cervix (Absence of Cervix Diagnosis Value Set) any time during the member's history through December 31 of the measurement year. Do not include laboratory claims (claims with POS 81). • Members who use hospice services (Hospice Encounter Value Set; Hospice Intervention Value Set) or elect to use a hospice benefit any time during the measurement year. Organizations that use the Monthly Membership Detail Data File to identify these members must use only the run date of the file to determine if the member elected to use a hospice benefit during the measurement year. • Members who die any time during the measurement year. • Members receiving palliative care (Palliative Care Assessment Value Set; Palliative Care Encounter Value Set; Palliative Care Intervention Value Set) any time during the measurement year. • Members who had an encounter for palliative care (ICD-10-CM code Z51.5) any time during the measurement year. Do not include laboratory claims (claims with POS 81). • Members with Sex Assigned at Birth of Male.

Administrative Specification

Denominator	The eligible population.
Numerator	The number of members~~women~~ recommended for routine cervical cancer screening who were screened for cervical cancer. Either of the following meets criteria: • ~~Women~~ Members 24–64 years of age as of December 31 of the measurement year who were recommended for routine cervical cancer screening who had cervical cytology (Cervical Cytology Lab Test Value Set; Cervical Cytology Result or Finding Value Set) during the measurement year or the 2 years prior to the measurement year. • ~~Women~~ Members 30–64 years of age as of December 31 of the measurement year who were recommended for routine cervical cancer screening who had cervical high-risk human papillomavirus (hrHPV)

testing (High Risk HPV Lab Test Value Set, High Risk HPV Test Result or Finding Value Set) during the measurement year or the 4 years prior to the measurement year ***and*** who were 30 years or older on the date of the test.

Note: *Evidence of hrHPV testing within the last 5 years also captures patients who had cotesting; therefore, additional methods to identify cotesting are not necessary.*

Hybrid Specification

Denominator A systematic sample drawn from the eligible population. Organizations may reduce the sample size using the current year's administrative rate or the prior year's audited rate. Refer to the *Guidelines for Calculations and Sampling* for information on reducing the sample size.

Numerator The number of members who were ~~women~~ recommended for routine cervical cancer screening ~~who~~ and were appropriately screened for cervical cancer, as documented through either administrative data or medical record review.

Administrative Refer to *Administrative Specification* to identify positive numerator hits from the administrative data.

Medical record Appropriate screenings are defined by any of the following:

- ~~Women~~ Members 24–64 years of age as of December 31 of the measurement year who were recommended for routine cervical cancer screening ~~who~~ and had cervical cytology during the measurement year or the 2 years prior to the measurement year.
  - Documentation in the medical record must include both of the following:
    - A note indicating the date when the cervical cytology was performed.
    - The result or finding. "Unknown" is not considered a result/finding.
  - Count any cervical cancer screening method that includes collection and microscopic analysis of cervical cells. Do not count lab results that explicitly state the sample was inadequate or that "no cervical cells were present"; this is not considered appropriate screening.
  - Do not count biopsies, because they are diagnostic and therapeutic only and are not valid for primary cervical cancer screening.

  Note: *Lab results that indicate the sample contained "no endocervical cells" may be used if a valid result was reported for the test.*
- ~~Women~~ Members 30–64 years of age as of December 31 of the measurement year who were recommended for routine cervical cancer screening ~~who~~and had cervical high-risk human papillomavirus (hrHPV) testing during the measurement year or the 4 years prior to the measurement year ***and*** who were 30 years or older as of the date of testing.
  - Documentation in the medical record must include both of the following:
    - A note indicating the date when the hrHPV test was performed. Generic documentation of "HPV test" can be counted as evidence of hrHPV test.

- The results or findings. ("Unknown" is not considered a result/ finding.

– Do not count biopsies, because they are diagnostic and therapeutic only and are not valid for primary cervical cancer screening.

Note: *Evidence of hrHPV testing within the last 5 years also captures patients who had cotesting.*

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table CCS-1/2: Data Elements for Cervical Cancer Screening

Metric	Data Element	Reporting Instructions	A
CervicalCancerScreening	CollectionMethod	Report once	✓
	EligiblePopulation	Report once	✓
	ExclusionAdminRequired	Report once	✓
	NumeratorByAdminElig	Report once	
	CYAR	(Percent)	
	MinReqSampleSize	Report once	
	OversampleRate	Report once	
	OversampleRecordsNumber	(Count)	
	ExclusionValidDataErrors	Report once	
	Denominator	Report once	
	NumeratorByAdmin	Report once	✓
	NumeratorByMedicalRecords	Report once	
	NumeratorBySupplemental	Report once	✓
	Rate	(Percent)	✓

Measure title	Cervical Cancer Screening	Measure ID	CCS, CCS-E
Description	The percentage of ~~women~~ members 21–64 years of age recommended for routine cervical cancer screening who were screened for cervical cancer using any of the following criteria: • ~~Women~~ Members 21–64 years of age who were recommended for routine cervical cancer screening and~~who~~ had cervical cytology performed within the last 3 years. • ~~Women~~ Members 30–64 years of age who were recommended for routine cervical cancer screening and~~who~~ had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years. • ~~Women~~ Members 30–64 years of age who were recommended for routine cervical cancer screening and~~who~~ had cervical cytology/high-risk human papillomavirus (hrHPV) cotesting within the last 5 years.		
Measurement period	January 1–December 31.		
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	  NCQA Customer Support: 888-275-7585 NCQA Fax: 202-955-3599 NCQA Website: www.ncqa.org Submit policy clarification support questions via My NCQA (http://my.ncqa.org)
Clinical recommendation statement	The U.S. Preventive Services Task Force (USPSTF) recommends screening for cervical cancer every 3 years with cervical cytology alone in women aged 21–29 years. This recommendation statement applies to all asymptomatic individuals with a cervix. –(A recommendation) The USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with hrHPV testing alone or every 5 years with hrHPV testing in combination with cytology (cotesting) in women aged 30–65 years. This recommendation statement applies to all asymptomatic individuals with a cervix. –(A recommendation) The USPSTF recommends against screening for cervical cancer in women younger than 21 years. This recommendation statement applies to all asymptomatic individuals with a cervix.– (D recommendation) The USPSTF recommends against screening for cervical cancer in women older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. This recommendation statement applies to all asymptomatic individuals with a cervix. (D recommendation) The USPSTF recommends against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion or cervical cancer. (D recommendation) The American Cancer Society recommends that individuals with a cervix initiate cervical cancer screening at age 25 years and undergo primary HPV testing every 5 years through age 65 years (preferred). If primary HPV testing is not available, individuals aged 25–~~-~~65 years should be screened with cotesting (HPV testing in combination with cytology) every 5 years or cytology alone every 3 years (acceptable) The recommendations apply to all asymptomatic individuals with a cervix, regardless of their sexual history or ~~human papillomavirus (~~HPV~~)~~ vaccination status, including those who have undergone supracervical

	hysterectomy and transgender men who retain their cervix. (Strong Recommendation). The Fenway Institute recommends that transgender and gender diverse patients who have a cervix have regular cervical pap tests, as per the published guidelines for cisgender women. The University of California San Francisco Center of Excellence for Transgender Health recommends that cervical cancer screening for transgender men, including intervals of screening and age to begin and end screening, follows recommendations for non-transgender women as endorsed by the American Cancer Society, the American Society of Colposcopy and Cervical Pathology ~~(ASCCP)~~, the American Society of Clinical Pathologists, the U.S. Preventive Services Task Force ~~(USPSTF)~~ and the World Health Organization.
Citations	American Cancer Society. (2020). *Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society.* https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21628 Fenway Health. (2021). *Medical Care of Trans and Gender Diverse Adults*. https://fenwayhealth.org/wp-content/uploads/Medical-Care-of-Trans-and-Gender-Diverse-Adults-Spring-2021-1.pdf University of California San Francisco Center of Excellence for Transgender Health. (2016). *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*. https://transcare.ucsf.edu/sites/transcare.ucsf.edu/files/Transgender-PGACG-6-17-16.pdf U.S. Preventive Services Task Force. 2018. "Screening for Cervical Cancer: U.S. Preventive Services Task Force Recommendation Statement." *JAMA* 320(7): 674–86.
Characteristics	
Scoring	Proportion.
Type	Process.
Stratification	• Cervical Cancer Screening. – Product line: ▪ Commercial. ▪ Medicaid.
Risk adjustment	None.
Improvement notation	A higher rate indicates better performance.
Guidance	**Allocation:** The member was enrolled with a medical benefit throughout the participation period.

	No more than one gap in enrollment of up to 45 days during each year of the participation period. To determine participation for a Medicaid beneficiary for whom enrollment is verified monthly, the member may not have more than a 1-month gap in coverage (i.e., a member whose coverage lapses for 2 months [60 days] is not considered enrolled during the participation period). The member must be enrolled on the last day of the measurement period. When identifying members in hospice, the requirements for identification of hospice members using the monthly membership detail data files are not included in the measure calculation logic and need to be programmed manually. **Reporting:** Commercial, Medicaid (report each product line separately). Product line stratifications are not included in the measure calculation logic and need to be programmed manually.
Definitions	
Participation	The identifiers and descriptors for each organization's coverage used to define members' eligibility for measure reporting. Allocation for reporting is based on eligibility during the participation period.
Participation period	Commercial: The measurement period and the 730 days prior to the measurement period. Medicaid: The measurement period.
Members recommended for routine cervical cancer screening	Members recommended for routine cervical cancer screening include members with: • Administrative Gender of Female (AdministrativeGender code Female) at any time in the member's history. • Sex Assigned at Birth (LOINC code 76689-0) of Female (LOINC code LA3-6) at any time in the member's history. • Sex for Clinical Use (LOINC code 99501-9) of Female or Specified during the measurement period.
Initial population	~~Women~~ Members 24–64 years of age recommended for routine cervical cancer screening by the end of the measurement period who also meet criteria for participation.
Exclusions	• Hysterectomy with no residual cervix (Hysterectomy With No Residual Cervix Value Set) anytime during the member's history through December 31 of the measurement year. • Cervical agenesis or acquired absence of cervix (Absence of Cervix Diagnosis Value Set) any time during the member's history through the end of the measurement period. Do not include laboratory claims (claims with POS 81)

	• Members who use hospice services (Hospice Encounter Value Set; Hospice Intervention Value Set) or elect to use a hospice benefit any time during the measurement period. Organizations that use the Monthly Membership Detail Data File to identify these members must use only the run date of the file to determine if the member elected to use a hospice benefit during the measurement period. • Members who die any time during the measurement period. • Members receiving palliative care (Palliative Care Assessment Value Set, Palliative Care Encounter Value Set, Palliative Care Intervention Value Set,) any time during the measurement period. • Members who had an encounter for palliative care (ICD-10-CM code Z51.5) anytime during the measurement year. Do not include laboratory claims (claims with POS 81). • Members with Sex Assigned at Birth of Male at any time in the patient's history.

Denominator	The initial population, minus exclusions.
Numerator	The number of ~~women~~ members who were screened for cervical cancer. Either of the following meets criteria: • ~~Women~~ Members 24–64 years of age by the end of the measurement period recommended for routine cervical cancer screening who had cervical cytology (Cervical Cytology Lab Test Value Set; Cervical Cytology Result or Finding Value Set) during the measurement period or the 730 days prior to the measurement period. • Members 30–64 years of age by the end of the measurement period recommended for routine cervical cancer screening who had cervical high-risk human papillomavirus (hrHPV) testing (High Risk HPV Lab Test Value Set, High Risk HPV Test Result or Finding Value Set) during the measurement period or the 4 years prior to the measurement period and who were 30 years or older on the date of the test. ***Note:*** *Evidence of hrHPV testing within the last 5 years also captures patients who had cotesting; therefore, additional methods to identify cotesting are not necessary.*
Data criteria (element level)	
Value sets: • CCSE_HEDIS_MY2023-2.0.0 – Absence of Cervix Diagnosis (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1522) – Cervical Cytology Lab Test (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1525) – Cervical Cytology Result or Finding (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1524) – High Risk HPV Lab Test (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1527) – High Risk HPV Test Result or Finding (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1526) – Hysterectomy With No Residual Cervix (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1523) • NCQA_Hospice-2.0.0 – Hospice Encounter (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1761) – Hospice Intervention (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1762) • NCQA_PalliativeCare-2.0.0 – Palliative Care Assessment (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2225) – Palliative Care Encounter (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.1450) – Palliative Care Intervention (https://www.ncqa.org/fhir/valueset/2.16.840.1.113883.3.464.1004.2224)	

Direct reference codes and codesystems:

- NCQA_PalliativeCare-2.0.0

– codesystem "ICD-10-CM": 'http://hl7.org/fhir/sid/icd-10-cm'
– code "Encounter for palliative care": 'Z51.5' from "ICD-10-CM" display 'Encounter for palliative care'

- NCQA_Terminology-2.0.0

– codesystem "ActCode": 'http://terminology.hl7.org/CodeSystem/v3-ActCode'
– codesystem "ConditionClinicalStatusCodes": 'http://terminology.hl7.org/CodeSystem/condition-clinical'
– code "active": 'active' from "ConditionClinicalStatusCodes"
– code "managed care policy": 'MCPOL' from "ActCode"
– code "retiree health program": 'RETIRE' from "ActCode"
– code "subsidized health program": 'SUBSIDIZ' from "ActCode"

Gender in Breast & Cervical Cancer Screening
Evidence Workup

NCQA seeks to promote health equity through performance measurement and strives to ensure that all individuals who need routine preventive screening are considered in the HEDIS®[1] measures Breast Cancer Screening and Cervical Cancer Screening. This evidence workup summarizes data standards for documentation and exchange of sex and gender data, as well as guidelines pertaining to breast and cervical cancer screening for transgender and gender-diverse patients.

Background

Approximately 1.6% of U.S. adults identify as transgender or nonbinary.[1] "Transgender" is an umbrella term often used to refer to people whose gender identity and sex assigned at birth do not correspond. Some individuals may identify as transgender, others may prefer or also identify with other terms like "non-binary," "gender diverse" or "genderqueer."[2] Transgender and gender-diverse patients systematically experience structural barriers to care, marginalization, discrimination and social stigma in the health care system, which result in disparities in care and poorer health outcomes. Structural barriers to care result in lower rates of preventive screenings for transgender and gender-diverse patients, compared to cisgender patients.[3]

Sex and Gender

Disparities for transgender and gender-diverse patients are exacerbated by the frequent misclassification of this population in data and the resulting exclusion from quality measurement and improvement efforts.[4] This occurs in part because sex and gender are often conflated, leading to the absence of sufficient context to accurately identify patient clinical need.

Conflation of Sex and Gender

"Sex" refers to the categories (male, female) to which people are typically assigned based on clinical traits—chromosomes, hormones or reproductive anatomy. It may be referred to by concepts such as sex assigned at birth, birth sex or sex recorded on original birth certificate, to provide context for estimation of a patient's clinical needs.

"Gender" refers to the intersection of an individual's gender identity (how an individual perceives themselves) and gender expression (how a person signals their gender to others)[5]—knowing this information (along with a patient's name and pronouns) can enable delivery of affirming and patient-centered care.

While these concepts are distinct and serve discrete functions, it is common for patients to be asked a single, nonspecific question about sex or gender. This can lead to confusion or discomfort for patients who have to interpret what is being asked.[6] A single-question approach can also lead clinicians and health plans to make assumptions about a patient's clinical needs or identity that may not be accurate. The use of a single sex/gender value is common throughout the health care system, including in how research is conducted, guidelines are developed and quality measures are specified.

[1]HEDIS® is a registered trademark of the National Committee for Quality Assurance.

Disaggregation of Sex and Gender

There are increasing calls to disaggregate sex and gender in clinical care and data collection. The U.S. Preventive Services Task Force (USPSTF) stated that it will consider both biological sex and gender identity when developing recommendations, and will clarify whether birth sex or gender identity should be used when determining the population to which recommendations apply.[7] The National Academies of Sciences, Engineering and Medicines (NASEM) issued a report, endorsed by 190 LGBTQIA+ organizations[8], recommending that both sex assigned at birth (when necessary) and gender identity be collected from patients.[9] The Fenway Health and Center for American Progress resource guide for collecting sexual orientation and gender identity (SOGI) data emphasizes that collection of both gender identity and sex assigned at birth is critical to delivering appropriate care to transgender patients.[10] These recommendations acknowledge that the conflation of sex and gender obscures patient clinical need, masks disparities in care and may not foster welcoming and affirming care environments. Disaggregation of sex and gender data may help better identify patient clinical need, such as breast and cervical cancer screening.

Breast Cancer Screening Guidelines and Evidence

Additional research is needed on the prevalence of breast cancer among transgender patients. Breast cancer rates for transgender men are not well described in the literature. Transgender women have a lower incidence of breast cancer, compared to cisgender women, but a higher incidence than cisgender men,[11] given potential increased risk from gender-affirming hormone exposure.[12,13] The duration of estrogen exposure at which risk increases is variable in the literature. In a nationwide retrospective study in the Netherlands, Blok et al. observed a median of 18 years of estrogen exposure at breast cancer diagnosis among transgender women.[14] Though not limited to transgender patients, the Nurse's Health Study found a statistically significant increase in breast cancer risk after 15 years of exposure to estrogen.[15] In addition, the median age for breast cancer diagnosis in transgender women is younger than observed in cisgender women, with some studies finding a median age of diagnosis at around 50 years of age (as compared to 60+ in cisgender women).[16]

Evidence indicates that breast cancer screening rates are lower among transgender adults recommended for screening as compared to their cisgender counterparts.[17] Missed preventive screenings may result in poorer outcomes like more advanced disease at diagnosis. Few studies have been conducted on the impact of missed breast cancer screening specifically among transgender patients, but studies have shown that absence of breast cancer screening in the general population can result in more advanced stage at diagnosis.[18] A study of survivorship among transgender and gender diverse cancer survivors found that this population experiences complex challenges and higher rates of risk factors for poor survival as compared to cisgender cancer survivors.[19] Breast cancer screening gaps for transgender individuals are influenced by barriers to access as well as lack of provider knowledge of screening guidelines for transgender patients.[20]

Guidelines recommend breast cancer screening for transgender and gender-diverse patients assigned female at birth or with breasts from natal puberty, as well as transgender and gender-diverse patients assigned male at birth with at least 5-10 years of exposure to gender-affirming estrogen therapy, excluding those with bilateral mastectomy or chest reconstruction.[21,22,23] See table 5 in the appendix for full recommendation statements.

Cervical Cancer Screening Guidelines and Evidence

Literature does not suggest a difference in prevalence of cervical cancer among transgender and gender-diverse patients as compared to the overall population, though there is evidence of care gaps. The 2016 National Transgender Survey found that most transmasculine individuals retain their cervix, but are not up to date with cervical cancer screenings.[24,25] Evidence indicates that transgender patients

recommended for cervical cancer screening may have lower rates of screening than their cisgender counterparts.[26] These gaps in care are driven by structural barriers to accessing care.[27]

Overall, guidelines for cervical cancer screening recommend screening for all patients with a cervix.[23,28,29,30] Screening is not recommended for patients who have had a hysterectomy and no longer have a cervix. Refer to Table 6 in the appendix for full guideline statements.

Data Standards

"Data standards" refers to a common set of agreed-on data elements and definitions that can be implemented in a standardized, structured and interoperable way. Data standards can support quality measurement by providing a common understanding of how data are defined, represented and shared across organizations, settings and systems.

The most accurate measure of routine screening needs is an anatomical inventory -- an individualized assessment of a patient's unique clinical characteristics. Anatomical inventories document the organs a patient has and help reduce the need to make assumptions about clinical needs based on gender identity.[31,32] However, they are not widely implemented across the health care system, and no data standards describe a standard approach for documenting and exchanging such data.

Several data standards relate to sex and gender, which may support identification of members recommended for routine breast and cervical cancer screening. Standards generally recommend collection of patient gender; most also recommend collection of sex-related data to support clinical care.

Fast Healthcare Interoperability Resources U.S. Core Implementation Guide

FHIR® is a data standard maintained by Health Level 7 (HL7). In the current FHIR *US Core Implementation Guide,* version 5.0.1, every patient profile must include a patient gender defined using the Administrative Gender data element and value set.[33]

Table 1: HL7 FHIR Data Standards

Data Element	Definition	Response Options	Standardized Terminology
Administrative Gender	The gender that the patient is considered to have for administration and record keeping purposes.	• Male • Female • Other • Unknown	SNOMED

Administrative Gender is a single gender value intended to be used for administrative purposes; it does not specify whether the value corresponds to gender identity or sex assigned at birth. The FHIR specification notes that additional, more specific sex or gender data, such as birth sex or gender identity, may be documented[34] using extensions.[2]

Administrative Gender is also the data element with which NCQA's HEDIS measures are specified. While this data element is broadly used by health plans to record member demographic data and understand member care needs, its ability to accurately identify patient clinical needs is limited because it does not clearly distinguish between patient sex and gender. As a result, health plans—and quality measures—that rely on this data element alone may incorrectly identify members and their care needs. In acknowledgment of these limitations, Fenway Health's *Do Ask Do Tell* toolkit recommends that Administrative Gender only be used for billing purposes and never for identifying patient needs or communicating with patients.[10]

[2]Extensions provide a standard way of documenting additional data beyond the minimum requirement.

United States Core Data for Interoperability

The United States Core Data for Interoperability (USCDI) outlines a standardized set of data elements for enabling interoperable exchange of health care data. USCDI is maintained by the Office of the National Coordinator for Health IT (ONC). Version 1 of the USCDI has been adopted as a health IT standard by the ONC.[35] As of December 31, 2022, health IT systems that are certified according to ONC health IT certification criteria must support USCDI version 1,[36,37] which includes a data element for documenting patient Sex Assigned at Birth.[38]

Table 2: USCDI Version 1 Standards

Data Element	Definition	Response Options	Standardized Terminology
Sex Assigned at Birth	The sex assigned to a patient at birth, typically based on observation of external anatomy.	• Male • Female • Unknown	SNOMED

National Academies of Sciences, Engineering and Medicine

NASEM published a consensus report recommending use of a two-step data collection approach in federal surveys. NASEM recommends collection of both sex assigned at birth and gender identity, but notes that sex assigned at birth should only be collected when clinically necessary. It also recommends asking about differences in sex development to assess intersex status, while acknowledging that more research is needed to determine a standard question to be used to assess status.

Table 3: NASEM Sex and Gender Data Collection Recommendations

Data Element	Definition	Response Options	Standardized Terminology
Sex Assigned at Birth	The sex assigned to a patient at birth, typically based on observation of external anatomy.	• Male • Female • Unknown	SNOMED
Differences in Sex Development/Intersex Status	Have you ever been diagnosed by a medical doctor or other health professional with an intersex condition or a difference of sex development (DSD) or were you born with (or developed naturally in puberty) genitals, reproductive organs, or chromosomal patterns that do not fit standard definitions of male or female?	• Yes • No • Don't Know • Prefer not to answer	None available

Gender Harmony Project

The Gender Harmony Project is an initiative of HL7 aimed at developing data standards for sex and gender. It recommends collection of a Sex for Clinical Use data element in addition to gender identity, name to use and pronouns. The "Sex for Clinical Use" sex classification applies to a particular clinical scenario. It encourages clinicians to reference specific clinical observations (anatomical inventory, hormone levels, chromosome analysis)[39] to determine the appropriate classification for a given clinical activity.

Table 4: Gender Harmony Project Data Standards

Data Element	Definition	Response Options	Standardized Terminology
Sex for Clinical Use	A summary sex classification element based on one or more clinical observations such as an organ survey, hormone levels, and chromosomal analysis	• Male • Female • Specified • Unknown	• LOINC • SNOMED

Harmonization of Data Standards

In 2022, participants in the Gender Harmony Project and NASEM recommendations co-authored a publication addressing harmonization between these standards. The authors conclude that the Gender Harmony Project data elements for gender identity and Sex for Clinical Use "provide the most flexibility and durability in sex/gender data collection."[40] At a minimum, organizations should collect these values, but may also collect Sex Assigned at Birth and intersex status, as outlined in the NASEM recommendations, to best support patient care.

Application of Data Standards to Measurement

Breast and cervical cancer screening are examples of clinical and measurement use cases for which existing methods of sex and gender data collection may misidentify patient screening needs. The Breast Cancer Screening and Cervical Cancer Screening measures assess screening among members with an administrative gender of female, which may result in exclusion of transgender and gender-diverse members who require screening but do not have an administrative gender of female, and vice versa. Data standards that enable collection of disaggregated sex- and gender-related data may improve accurate identification of patients recommended for routine screening in such use cases.

Appendix

Table 5: Breast Cancer Screening Guidelines

Population	Recommendation	Grade
United States Preventive Services Task Force (2016) [41]		
Women 50-74	The USPSTF recommends biennial screening mammography for women aged 50 to 74 years	B • The USPSTF recommends the service. There is high certainty thatthe net benefit is moderate or there is moderate certainty thatthe net benefit is moderate to substantial.
University of California San Francisco Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (2016)[28]		
Transgender women	It is recommended that screening mammography be performed every 2 years, once the age of 50 and 5-10 years of feminizing hormone use criteria have been met. Screening mammography is the primary recommended modality for breast cancer screening in transgender women	Grading: T O W • T: At least some data in transgender population • O: Strongest available evidence is from observational studies • W: Weak
Transgender men	Transgender men who have not undergone bilateral mastectomy, or who have only undergone breast reduction, should undergo screening according to current guidelines for non-transgender women.	No grading. Grading of guidelines for non-transgender women apply.
Fenway Medical Care of Transgender and Gender Diverse Adults (2021)[42]		
Transgender and gender-diverse patients assigned female at birth	In patients assigned female at birth (AFAB) who have not undergone chest reconstruction (including those who have had breast reduction), breast/chest screening recommendations are the same as for cisgender women of a similar age and medical history	Consensus-based
Transgender and gender-diverse patients on estrogen	In TGD patients on estrogen, consider initial screening mammography starting at age 50, and only once on estrogen therapy for greater than 5 years. Thereafter mammograms are recommended every two years, following screening guidelines for cisgender women.	Consensus-based
World Professional Association for Transgender Health (WPATH) Standards of Care Version 8 (2022)[23]		
Transgender and gender-diverse patients who have	We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people who have	Grade: Strong recommendation.

received estrogens	received estrogens, taking into consideration the length of time of hormone use, dosing, current age, and the age at which hormones were initiated.	Strong recommendations ("we recommend") are for those interventions/therapy/strategies where: • The evidence is of high quality • Estimates of the effect of an intervention/therapy/ strategy (i.e., there is a high degree of certainty effects will be achieved in practice) • There are few downsides of therapy/intervention/ strategy • There is a high degree of acceptance among providers and patients or those for whom the recommendation applies.
Transgender and gender-diverse patients without chest surgery	We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.	Strong recommendations ("we recommend") are for those interventions/therapy/strategies where: • The evidence is of high quality • Estimates of the effect of an intervention/therapy/ strategy (i.e., there is a high degree of certainty effects will be achieved in practice) • There are few downsides of therapy/intervention/ strategy • There is a high degree of acceptance among providers and patients or those for whom the recommendation applies.

Table 6: Cervical Cancer Screening Guidelines

Population	Recommendation	Grade
United States Preventive Services Task Force Cervical Cancer Screening Recommendation[43]		
Women aged 21 to 65 years* *This recommendation statement applies to all asymptomatic individuals with a cervix	The USPSTF recommends screening for cervical cancer every 3 years with cervical cytology alone in women aged 21 to 29 years. For women aged 30 to 65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting).	Grade: A The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
UCSF Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (2016)[28]		
Transgender men	Cervical cancer screening for transgender men, including interval of screening and age to begin and end screening follows recommendations for non-transgender women as endorsed by the American Cancer Society, American Society of Colposcopy and Cervical Pathology (ASCCP), American Society of Clinical Pathologists, U.S. Preventive Services Task Force (USPSTF) and the World Health Organization.	Grade: X C S X: No data (expert opinion only) C: Consensus expert opinion S: Strong
Fenway Medical Care of Transgender and Gender Diverse Adults (2021)[22]		

Transgender and gender-diverse patients	TGD patients who have a cervix are recommended to have regular cervical pap tests as per the published guidelines for cisgender women	Consensus-based
World Professional Association for Transgender Health (WPATH) Standards of Care Version 8 (2022)[23]		
Transgender and gender-diverse patients	We recommend health care professionals offer cervical cancer screening to transgender and gender diverse people who currently have or previously had a cervix folowing local guidelines for cisgender women.	Grade: Strong Recommendation Strong recommendations ("we recommend") are for those interventions/therapy/strategies where: • The evidence is of high quality • Estimates of the effect of an intervention/therapy/ strategy (i.e., there is a high degree of certainty effects will be achieved in practice) • There are few downsides of therapy/intervention/ strategy • There is a high degree of acceptance among providers and patients or those for whom the recommendation applies.
American Cancer Society (2020) [30]		
Asymptomatic individuals with a cervix, including those who have undergone supracervical hysterectomy and transgender men who retain their cervix, aged 25-65	The ACS recommends that individuals with a cervix initiate cervical cancer screening at age 25 years and undergo primary HPV testing every 5 years through age 65.	Strong recommendation. A strong recommendation conveys the consensus that the benefits of adherence to that intervention outweigh the undesirable effects that may result from screening.

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