Coding Implications
Revision log

CONCERT ONCOLOGY TESTING: CANCER SCREENING AND SURVEILLANCE

See Important Reminder at the end of this policy for important regulatory and legal information.

OVERVIEW

This policy addresses the use of genetic and biomarker tests that aim to screen for specific cancers in individuals who are at risk to develop them. These genetic and biomarker screening tests can be designed for asymptomatic individuals that are at an average risk level for cancer, or for individuals that are known to be at a higher risk of developing a specific cancer.

For additional information see the Background and Rationale section.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage.

POLICY REFERENCE TABLE

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CRITERIA

It is the policy of health plans affiliated with Centene Corporation® that the specific tests noted below are **medically necessary** when meeting the related criteria:

COLORECTAL CANCER SCREENING TESTS

FIT-DNA Testing (Stool DNA Testing)

I. The use of FIT-DNA Testing (stool DNA testing) to screen for colorectal cancer may be considered medically necessary when:

A. The member/enrollee is 45 years of age or older, **AND**

B. The member/enrollee is an individual who is at average risk for colorectal cancer, because the member/enrollee does not have any of the following:

1. A personal history of colorectal cancer or adenoma or sessile serrated polyp, **OR**
2. A family history of colorectal cancer in close relatives, **OR**
3. A personal history of inflammatory bowel disease (ulcerative colitis or Chron's disease), **OR**

4. A personal history of cystic fibrosis, **OR**
5. A confirmed or suspected hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC), **OR**
6. A personal history of receiving radiation to the abdomen (belly) or pelvic area to treat a prior cancer, **OR**
7. Symptoms suspicious for an undiagnosed colorectal cancer (e.g., rectal bleeding, iron deficiency anemia, abdominal pain, weight loss).

II. Current evidence does not support the use of FIT-DNA Testing (stool DNA testing) to screen for colorectal cancer for all other indications.

NOTE: Fecal immunochemical testing (FIT) alone is not in the scope of this policy (see definitions)

Urinary Biomarker Tests for Precancerous Colon Polyps

I. Current evidence does not support the use of urinary biomarker tests for precancerous colon polyps for all indications.

Blood-based Biomarker Colorectal Cancer Screening Tests

I. Current evidence does not support the use of blood-based biomarkers to screen for colorectal cancer for all indications.

LUNG CANCER SCREENING TESTS

Blood-based Biomarker Lung Cancer Screening Tests

I. Current evidence does not support the use of blood-based biomarker tests for lung cancer screening for all indications.

CA-125 (CANCER ANTIGEN 125) TESTS

CA-125 (Cancer Antigen 125) Tests

I. CA-125 (cancer antigen 125) tests are considered medically necessary when:

A. The member/enrollee meets one of the following:

1. The member/enrollee has signs or symptoms concerning for possible abdominal cancer (e.g., pelvic mass, ascites, bloating, urinary frequency, inguinal nodes), OR

2. The member/enrollee has one of the following:

a) Ovarian cancer, OR

b) Endometrial cancer, OR

c) Appendiceal adenocarcinoma, OR

d) Uterine neoplasms, OR

3. The member/enrollee has a genetic predisposition for ovarian cancer development (e.g., *BRCA2* germline mutation), AND

a) The member/enrollee is undergoing preoperative planning for a bilateral salpingo-oophorectomy (BSO) or salpingectomy.

II. Current evidence does not support the use of CA-125 (cancer antigen 125) tests for all other indications, including:

A. Asymptomatic members/enrollees at average risk for cancer.

PROSTATE SPECIFIC ANTIGEN (PSA) TESTS

Prostate Specific Antigen (PSA) Tests

I. Prostate Specific Antigen (PSA) tests[1] are considered medically necessary when:

A. The member/enrollee is between the ages of 40 and 75 years, AND

    1. One of the following high-risk factors for prostate cancer development is present:

        a) Is Black/African American, OR

        b) Has a genetic variant associated with increased risk for prostate cancer, OR

        c) Has a family history of prostate cancer, AND

    2. One of the following:

        a) Has not received PSA testing in the past year, OR

        b) Is under 70 years of age, AND

            (1) Is being assessed for testosterone therapy for hypogonadism, AND

                (a) Has not yet initiated treatment, OR

                (b) Initiated treatment in the last 3 to 12 months, OR

B. The member/enrollee is between the ages of 45 and 75 years, AND

    1. Has not received PSA testing in the past 2 years, OR

C. The member/enrollee is between the ages of 55 and 69 years, AND

    1. Is being assessed for testosterone therapy for hypogonadism, AND

        a) Has not yet initiated treatment, OR

        b) Initiated treatment in the last 3 to 12 months, OR

D. The member/enrollee is older than 75 years, AND

    1. The member/enrollee has a life expectancy greater than or equal to 10 years, OR

    2. Has never undergone PSA testing, OR

E. The member/enrollee has a history of elevated or rising PSA levels, AND

    1. Has not received testing in the past six months, OR

F. The member/enrollee is receiving a repeat PSA test to confirm a previous result indicating elevated PSA, OR

G. The member/enrollee has received a diagnosis of atypical small acinar proliferation (ASAP; also known as "atypia"), high-grade prostatic intraepithelial neoplasia (HGPIN), or a benign result from a biopsy, AND

1. The member/enrollee has not received testing in the past 12 months, OR

H. The member/enrollee has a current or past diagnosis of prostate cancer, OR

I. The member/enrollee has symptoms that may indicate early prostate cancer (i.e. slow urination, weak urinary stream, increased urinary frequency, hematuria, hematospermia, or erectile dysfunction).

II. Current evidence does not support the use of measurement of free PSA as a first-line screening test in asymptomatic individuals, except when performed as an automatic reflex from abnormal initial total PSA measurement.

III. Current evidence does not support the use of prostate specific antigen (PSA) tests for all other indications.

[1]PSA testing for screening in asymptomatic individuals includes measuring total prostate-specific antigen, with optional automatic reflex testing for free prostate-specific antigen.

CERVICAL CANCER (PAP SMEAR) SCREENING TESTS

Cervical Cancer Screening (Pap Smear) Tests

I. Cervical cancer screening (Pap smear) tests are considered medically necessary when:

A. The member/enrollee has NOT had a hysterectomy with removal of the cervix for benign reasons, AND

1. The member/enrollee is between the ages of 21 and 65 years, AND

a) Has not received a cervical cancer screening test (Pap smear) WITHOUT paired HPV testing in the past 3 years, AND

b) Has not received a cervical cancer screening test (Pap smear) WITH paired HPV testing in the past 5 years, OR

2. The member/enrollee is older than age 65 years, AND

a) Has a history of cervical cancer, OR

b) Has a history of CIN2 (cervical intraepithelial neoplasia 2) or greater within the past 20 years, OR

c) Has not received recommended cervical cancer screening prior to age 65 years, OR

3. The member/enrollee is being retested after a previously unsatisfactory cytology result, OR

4. The member/enrollee has signs/symptoms of possible cervical cancer (e.g., vaginal bleeding, postcoital bleeding, pelvic and/or lower back pain), OR

5. The member/enrollee has HIV infection, AND

   a) Is older than 21 years of age, OR

6. The member/enrollee is immunosuppressed, AND

   a) Is older than 21 years of age, AND

      (1) Has fewer than 3 consecutive negative annual cytology results, AND

      (2) Has not received a cervical cancer screening test (Pap smear) in the past year, OR

7. The member/enrollee has a history of exposure to diethylstilbestrol *in utero,* AND

   a) Has not received a cervical screening test in the past year, OR

B. The member/enrollee meets BOTH of the following:

1. Has a history of any of the following:

   a) Cervical cancer, OR

   b) Vulvar cancer, OR

   c) Vaginal cancer, AND

2. Has not received a cervical cancer screening test in the past year, OR

C. The member/enrollee meets BOTH of the following:

1. Has a prior screening result showing one of the following HIGH RISK dysplasias:

a) Atypical squamous cells - cannot exclude high-grade squamous intraepithelial lesion (ASC-H), OR

b) High-grade squamous intraepithelial lesion (CIN2 or CIN3), OR

c) Adenocarcinoma in situ, AND

2. Has not received a cervical cancer screening test in the past 6 months, OR

D. The member/enrollee meets BOTH of the following:

1. Has a prior screening result showing one of the following LOW RISK dysplasias:

a) Atypical squamous cells of uncertain significance (ASC-US), OR

b) Low-grade squamous intraepithelial lesion (CIN1), OR

c) Atypical endocervical cells - not otherwise specified (AEC-NOS), OR

d) Atypical glandular cells - not otherwise specified (AGC-NOS), AND

2. Has not received a cervical cancer screening test in the last 12 months, OR

E. The member/enrollee has a prior negative screening result indicating lack of transformation zone, AND

1. Is age 30 years or older, AND

a) Has tested positive for HPV, AND

(1) Has not received a cervical cancer screening test in the last 12 months, OR

b) Has unknown HPV status, AND

(1) Has not received a cervical cancer screening test in the last 3 years, OR

F. The member/enrollee is otherwise identified to have an immediate CIN3+ risk less than or equal to 4%, AND

1. Has a 5 year CIN3+ risk of ≥ 0.55%, AND

a) Has not received a cervical cancer screening test in the last 12 months, OR

2. The member/enrollee has a 5 year CIN3+ risk of 0.15 - 0.54%, AND

a) Has not received a cervical cancer screening test in the last 3 years, OR

3. The member/enrollee has a 5 year CIN3+ risk of < 0.15%, AND

a) Has not received a cervical cancer screening test in the last 5 years.

II. Cervical cancer screening tests (Pap smears) are considered investigational for all other indications, including:

A. Screening for bacterial vaginitis/vaginosis.

MULTI-CANCER EARLY DETECTION SCREENING TESTS

Multi-Cancer Early Detection Screening Tests

I. Current evidence does not support the use of multi-cancer early detection screening for all indications.

BACKGROUND AND RATIONALE

FIT-DNA Testing (Stool DNA Testing)

National Comprehensive Cancer Network (NCCN): Colorectal Cancer Screening (2.2025)
This guideline recommends the Fecal immunochemical test (FIT) for colorectal cancer (CRC) screening in average-risk individuals aged 45-75 with no personal history of pre-cancerous polyps, irritable bowel disease (IBD), high-risk germline condition, cystic fibrosis, childhood cancer, and no family history of advanced precancerous polyps in a first-degree relative or close relatives with CRC (CSCR-1). The individual must also have a life expectancy greater than or equal to 10 years (p. CSCR-1A).

NCCN states that symptoms associated with CRC may include rectal bleeding, iron deficiency anemia, abdominal pain or weight loss, and that a rectal exam and colonoscopy should be considered for all patients with these symptoms (regardless of age). Colonoscopy is the preferred screening method for individuals at increased risk. The choice of screening modality should be based on patient preference and availability after discussion (p. CSCR-1 and CSCR-2).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf

Food and Drug Administration (FDA)

Cologuard (Exact Sciences):

On August 12, 2014, Cologuard (Exact Sciences) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process as an automated fecal DNA testing product (P130017). Cologuard is intended for the qualitative detection of colorectal neoplasia associated with DNA markers and occult hemoglobin in human stool. A positive result may indicate the presence of CRC or advanced adenoma and should be followed by diagnostic colonoscopy (p. 1).

On September 20, 2019, the FDA approved the expansion of the Cologuard label to include adults ages 45 years or older. Cologuard was previously indicated for those aged 50 years or older. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

U.S Food and Drug Administration. Summary of Safety and Effectiveness Data for Cologuard (PMA No. P130017). FDA website. Approved August 11, 2014.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p130017

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Urinary Biomarker Tests for Precancerous Colon Polyps

National Comprehensive Cancer Network (NCCN): Colorectal Cancer Screening (2.2025)

This guideline does not include a recommendation for colorectal cancer (CRC) screening via urine-based screening methods for individuals of average risk for CRC (p. CSCR-2).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf

Concert Note
There is insufficient evidence of clinical utility to support the routine use of these tests in clinical care. A search for guidelines, position statements, systematic reviews, and consensus statements regarding the use

of urinary biomarker tests for precancerous colon polyps was performed in April 2025, and no conclusive, objective support was identified. The following guideline bodies were assessed for relevant guidance: National Comprehensive Cancer Network.

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Blood-based Biomarker Colorectal Cancer Screening Tests

Concert Evidence Review for Coverage Determination (Published 08/15/2025)

This review focused on a search for evidence-based guidelines and peer-reviewed, published evidence of the clinical validity and clinical utility of blood-based biomarker colorectal cancer screening from 11/14/2025 to 7/22/2025. A total of 121 abstracts were identified and 26 references were fully reviewed, 1 of which met the inclusion criteria. This prospective, multicenter, cross-sectional observational study (PREEMPT CRC study) performed by Shaukat et al evaluated the clinical performance of a blood-based circulating tumor DNA test (Freenome) intended to screen for colorectal cancer in an average risk population. A cohort of 27,010 eligible participants were included in the analysis. The blood test demonstrated 79.2% sensitivity for colorectal cancer, and 91.5% specificity or advanced colorectal neoplasia. All participants underwent a colonoscopy. The study concluded that this blood-based test provides acceptable accuracy in detecting colorectal cancer, but the sensitivity at detecting advanced precancerous neoplasms was low at 12.5%.

Multiple previous studies have been published on BeScreened, FirstSight CRC, ColonSentry, Colovantage, ColoScape Colorectal Cancer Detection, and Guardant Shield and their ability to screen for increased risk of colorectal cancer, including several meta-analyses and validation studies. These studies include a measure of clinical validity measured by sensitivity and specificity, and several studies compared these measures to those of colonoscopy, FIT or FOBT testing. The evidence for clinical validity does not consistently demonstrate superior sensitivity or specificity for these tests across studies. This lack of consistency highlights the importance of understanding the mechanism of these biomarkers in colorectal cancer in order to explain the observed variability.

Further, there is limited short or long term evidence to demonstrate that these tests promote a safe and effective alternative to colonoscopy or useful screening test to prioritize patients who should get colonoscopies. While the National Comprehensive Cancer Network (NCCN) addresses blood-based tests for colon cancer screening in their most recent recommendations (2.2025), they do so in moderate terms with very specific stipulations about the appropriateness of the use of these tests.

There is **INSUFFICIENT EVIDENCE** in published guidelines and peer-reviewed literature to definitively demonstrate improved health outcomes from the use of blood-based biomarker colorectal cancer screening, such as Shield (Guardant Health), FirstSight (CellMax Life), and ColoVantage (Quest Diagnostics), as compared to the current standard of care. At this time, the available evidence does not

support health plan coverage of these tests, in part due to lack of strong support, or absence of support, present in current existing professional society guidelines (USPSTF).

Concert. Evidence Review for Coverage Determination for ColoRectal Cancer Blood Based Biomarker Tests. Published 08/15/2025.

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Blood-based Biomarker Lung Cancer Screening Tests

National Comprehensive Cancer Network (NCCN): Lung Cancer Screening (1.2025)
This guideline does not include a recommendation for lung cancer screening via blood-based or micro-RNA based screening.
National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening 1.2025 https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

Concert Note
There is insufficient evidence of clinical utility to support the routine use of these tests in clinical care. A search for guidelines, position statements, systematic reviews, and consensus statements regarding the use of blood-based biomarker lung cancer screening tests was performed in April 2025 and no conclusive, objective support was identified.

CA-125 (Cancer Antigen 125) Tests

National Comprehensive Cancer Network (NCCN): Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate (1.2026)

This guideline recommends CA-125 as part of preoperative planning for bilateral salpingo-oophorectomy (BSO) or salpingectomy in individuals with germline *BRCA* pathogenic or likely pathogenic variants (p. BRCA-A 2-3 of 5).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate 1.2026
https://www.nccn.org/professionals/physician_gls/pdf/genetics_bopp.pdf

National Comprehensive Cancer Network (NCCN): Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric (1.2025)

This guideline recommends CA-125 for preoperative planning for BSO or salpingectomy in individuals with germline *MLH1*, *MSH2*, *MSH6*, *EPCAM*, or *PMS2* mutations (p. LS-B 4 of 5, LS-C 4 of 5, LS-D 4 of 5, LS-E 4 of 5).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric 1.2025 https://www.nccn.org/professionals/physician_gls/pdf/genetics_ceg.pdf

National Comprehensive Cancer Network (NCCN): Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer (3.2025)

This guideline recommends CA-125 testing in several clinical scenarios:

- Suspected ovarian cancer diagnosis based on the presence of various features such as a palpable abdominal mass, bloating, or urinary frequency (p. OV-1)
- Newly diagnosed ovarian cancer (p. OV-3)
- Ovarian cancer at any stage following treatment (p. OV-6)
- Complete remission and relapse at or greater than 6 months post-treatment in platinum-sensitive disease (p. OV-8)
- Low grade serous carcinoma monitoring for recurrence (p. LCOC-7)
- Ovarian serous borderline epithelial tumors of low malignant potential (p. LCOC-10)
- Endometrioid adenocarcinoma (p. LCOC-5, OV-6).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer 3.2025 https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

National Comprehensive Cancer Network (NCCN): Uterine Neoplasms (3.2025)

This guideline recommends consideration of CA-125 testing during the initial evaluation of all uterine neoplasms (p. UN-1), as well as suspected extrauterine disease of endometrial carcinoma (p. ENDO-3). The guideline also recommends CA-125 during surveillance for endometrial carcinoma if it was initially elevated (p. ENDO-9) and for suspected extrauterine disease in patients with endometrioid endometrial carcinoma (p. ENDO-3).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms 3.2025 https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

National Comprehensive Cancer Network (NCCN): Colon Cancer (4.2025)

This guideline recommends consideration of CA-125 testing for individuals with appendiceal adenocarcinoma, especially if CEA and CA-19-9 are normal (p. COL-I 1 of 3).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colon Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf

National Comprehensive Cancer Network (NCCN): Occult Primary (2.2025)

This guideline recommends CA-125 testing for adenocarcinoma or carcinoma not otherwise specified in those with a uterus and/or ovaries in the setting of a peritoneal presentation or ascites (p. OCC-4) or inguinal nodes (p. OCC-5).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Occult Primary 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/occult.pdf

American College of Obstetrics and Gynecology (ACOG)

The ACOG committee opinion number 716 (published 2017; reaffirmed in 2024) states that "the use of transvaginal ultrasonography and tumor markers (such as CA-125), alone or in combination, for early detection of ovarian cancer in average-risk women have not been proved to reduce mortality, and harms exist from invasive diagnostic testing (e.g., surgery) resulting from false-positive test results" (p. 1).

Committee Opinion No. 716: The Role of the Obstetrician-Gynecologist in the Early Detection of Epithelial Ovarian Cancer in Women at Average Risk. Obstet Gynecol. 2017;130(3):e146-e149. doi:10.1097/AOG.0000000000002299

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Prostate Specific Antigen (PSA) Tests

National Comprehensive Cancer Network (NCCN): Prostate Cancer Early Detection (2.2025)

For individuals at average risk, this guideline recommends beginning prostate cancer early detection including prostate-specific antigen (PSA) screening at age 45. In the absence of additional risk factors, such as elevated or rising PSA levels, these individuals are recommended to undergo repeat testing every 2 to 4 years (p. PROSD-2).

The guidelines further specify that testing in individuals over age 75 should only be done for those who are very healthy with no comorbidities, and testing is not recommended for individuals with a life expectancy of less than 10 years (p. MS-12 to MS-13).

Individuals with an elevated PSA result are recommended to receive a repeat PSA during the pre-biopsy workup (p. PROSD-3, MS-17).

Those with previously elevated PSA levels are recommended to have repeat testing at 1- to 2-year intervals (p. PROSD-2).

Individuals who undergo a pre-workup for a potential biopsy but are found to have a low suspicion for clinically significant cancer are recommended to follow up in 6 months.

Individuals with atypia, HGPIN, or benign prostate biopsy results are recommended to have follow-up PSA and DRE tests every 12 to 24 months, with additional biomarker testing or mpMRI advised if a prior high-quality mpMRI has not been performed (p. PROSD-4, MS-34).

The guideline further recommends that PSA testing begin at age 40 for individuals identified as high risk. These high-risk individuals include:

- Black/African American individuals
- Individuals with germline mutations that increase the risk for prostate cancer

For individuals at increased risk, the guidelines recommend repeat testing at 1- to 2-year intervals (p. PROSD-2).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf

National Comprehensive Cancer Network (NCCN): Prostate Cancer (2.2025)

This guideline recommends the collection of PSA during the initial workup for a prostate cancer diagnosis (p. PROS-1).

For patients electing active surveillance, the NCCN recommends the following PSA monitoring schedules:

- For patients with N1 disease on androgen deprivation therapy (ADT), a PSA test every 3–6 months.
- For patients with localized disease under observation, a PSA test every 6–12 months for the first 5 years, then annually thereafter (p. PROS-9).

During prostate cancer treatment, the NCCN generally recommends consistent monitoring of PSA levels (p. PROS-1 to PROS-15).

The NCCN recommends the use of free PSA testing only to calculate the ratio of total to free prostate-specific antigen when a patient has an elevated total PSA result, where the aim is to improve the specificity of prostate cancer detection (PROS-3, MS-22).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

National Comprehensive Cancer Network (NCCN): Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate (1.2026)

This guideline lists the following genes as being associated with an inherited predisposition to prostate cancer: *ATM, BRCA1, BRCA2, CHEK2, HOXB13, TP53* (p. CRIT-6A, GENE-A).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate 1.2026 https://www.nccn.org/professionals/physician_gls/pdf/genetics_bopp.pdf

National Comprehensive Cancer Network (NCCN): Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric (1.2025)

This guideline states that the following Lynch syndrome genes are associated with an inherited predisposition to prostate cancer and may warrant consideration of enhanced prostate cancer screening: *MLH1, MSH2, EPCAM, MSH6,* and *PMS2* (p. LS-B 5 of 5, LS-C 5 of 5, LS-D 5 of 5, LS-E 5 of 5).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric 1.2025 https://www.nccn.org/professionals/physician_gls/pdf/genetics_ceg.pdf

American Cancer Society (ACS)

In the article "Prostate Cancer Early Detection, Diagnosis, and Staging" under the section "Signs and Symptoms of Prostate Cancer," the American Cancer Society states that, while most early prostate cancer diagnosis do not cause symptoms, symptoms of early prostate cancer include problems with urination, blood in semen or urine, and erectile dysfunction.

Prostate cancer signs and symptoms. American Cancer Society. https://www.cancer.org/cancer/types/prostate-cancer/detection-diagnosis-staging/signs-symptoms.html. Last revised: November 22, 2023.

Endocrine Society

For the administration of testosterone therapy for hypogonadism, The Endocrine Society recommends that for men 55–69 years and men 40–69 years at increased risk for prostate cancer undergoing prostate monitoring, a PSA test and digital rectal exam should be performed before initiating treatment, 3–12 months after initiation, and then according to age- and race-specific prostate cancer screening guidelines after a year (Table 9, p. 1735).

Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744. doi: 10.1210/jc.2018-00229.

American Urological Association (AUA) and Society of Urologic Oncology (SUO)

In a 2023 joint guideline on the early detection of prostate cancer, the AUA and SUO direct clinicians to initiate PSA screening as follows:

- To average risk people beginning at age 50
- To people at increased risk, which includes those with predisposing germline mutations, Black ancestry, and a strong family history of prostate cancer, every 2 to 4 years beginning at age 40-45 years (p. 2).

For individuals age 70 or older, the joint guideline recommends shared decision making taking into account the patient's personal history and preferences in determining when to discontinue screening, but does not provide a specific age cutoff (p. 13).

This guideline also indicates that while there is no single agreed upon definition of a high-risk or concerning family history, the presence of a first degree relative with prostate cancer, two or more total relatives with prostate cancer especially if one is diagnosed before age 60, metastatic prostate cancer, or prostate cancer related death are all considered reasonable indicators of an increased risk to develop prostate cancer (p.11).

Wei JT, Barocas D, Carlsson S, et al. Early Detection of Prostate Cancer: AUA/SUO Guideline Part I: Prostate Cancer Screening. J Urol. 2023;210(1):46-53. doi:10.1097/JU.0000000000003491

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Cervical Cancer Screening (Pap Smear) Tests

United States Preventive Services Task Force (USPSTF)

In their updated 2018 guidelines for cervical cancer screening, the USPSTF states the following:

"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)" (p. 674).

US Preventive Services Task Force. Screening for cervical cancer: US Preventive Services Task Force recommendation statement. JAMA. 2018;320(7):674-686. doi:10.1001/jama.2018.10897

American Cancer Society (ACS)

In a 2020 cervical cancer screening guideline update, the ACS recommends that cervical cancer screening be discontinued after age 65 for individuals with a cervix and without a history of CIN2 or greater in the past 25 years (p. 332).

Fontham ETH, Wolf AMD, Church TR, et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. CA Cancer J Clin. 2020;70(5):321-346. doi:10.3322/caac.21628

National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), HIV Medicine Association (HIVMA), and Infectious Diseases Society of America (IDSA)

In the jointly authored "Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV," the NIH, CDC, HIVMA, and IDSA recommend the following for cervical cancer screening in individuals with a potential HIV diagnosis:

"People aged 21 to 29 years with HIV should have cervical cytology at the time of initial diagnosis with HIV" (p. Q-7).

Routine cervical cancer screening recommendations for individuals with HIV include:

- **<21 Years**: No screening recommended.
- **21–24 Years**: Cytology only, performed yearly. If 3 consecutive annual cytology tests are normal, adjust screening to every 3 years.
- **25–29 Years**: Cytology only, performed yearly. If 3 consecutive annual cytology tests are normal, adjust screening to every 3 years.

- **≥30 Years**: Co-testing (cytology + hr-HPV) performed yearly. If both cytology and hr-HPV are negative for 3 consecutive years, adjust screening to every 3 years. Alternatively, cytology only can be performed yearly, and if 3 consecutive annual cytology tests are normal, adjust to every 3 years (p. Q-9).

Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. National Institutes of Health, HIV Medicine Association, and Infectious Diseases Society of America. Last update April 23, 2025. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection.

UpToDate

Authors of the review entitled "Outcome and follow-up of diethylstilbestrol (DES) exposed individuals" recommend annual screening for those exposed to DES while *in utero*.

Hatch E, Karam A. Outcome and follow-up of diethylstilbestrol (DES) exposed individuals. In: Connor RF, ed. UpToDate. Wolters Kluwer; Updated June 6, 2024. https://www.uptodate.com/contents/outcome-and-follow-up-of-diethylstilbestrol-des-exposed-individuals

National Comprehensive Cancer Network (NCCN): Vulvar Cancer (1.2025)

This guideline recommends consideration of screening for human papilloma virus (HPV) and cytology testing during workup for vulvar cancer (p. VULVA-1).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer 1.2025 https://www.nccn.org/professionals/physician_gls/pdf/vulvar.pdf

National Comprehensive Cancer Network (NCCN): Vaginal Cancer (5.2025)

This guideline recommends annual cytology screening (with possible inclusion of HPV testing) during follow up and surveillance for individuals with a history of vaginal cancer (p. VAG-4, MS-11), although the effectiveness of cytology in detecting recurrent cancer is limited. Footnotes highlight that cytology accuracy may be compromised in patients who have received pelvic radiation (p. VAG-4).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Vaginal Cancer 5.2025 https://www.nccn.org/professionals/physician_gls/pdf/vaginal.pdf

National Comprehensive Cancer Network (NCCN): Cervical Cancer (4.2025)

This guideline recommends the following:

Annual cytology screening is suggested for the detection of lower genital tract neoplasia, particularly in immunocompromised patients. However, cytology alone has limited utility for detecting recurrent cervical cancer, especially in asymptomatic cases. As in vaginal cancer, the accuracy of cytology results may be affected in patients who have undergone pelvic radiation (p. CERV-10).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer 4.2025 https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf

American Society for Colposcopy and Cervical Pathology (ASCCP)

In a 2023 update to their 2019 guidelines entitled, "2019 ASCCP Risk-Based Management Consensus Guidelines: Updates Through 2023", the ASCCP recommends repeating age-based screening as soon as convenient and no later than 4 months after initial unsatisfactory results (p. 4).

Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines: Updates Through 2023. J Low Genit Tract Dis. 2024;28(1):3-6. doi:10.1097/LGT.0000000000000788

In the 2019 "ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors", the following recommendations are made based on atypical cytology and/or histology results:

Patients with a CIN3+ less than 4% should be evaluated for 5-year CIN3+ risk:

- If CIN3+ risk is greater than or equal to 0.55%, the patient should return for cervical cancer rescreening in 1 year.
- If CIN3+ risk is between 0.15% and 0.54%, the patient should return for cervical cancer rescreening in 3 years.
- If CIN3+ risk is less than 0.15%, the patient should return for cervical cancer rescreening in 5 years (p. 109).

For the management of low-grade cytology or histology results without progression to high-grade abnormalities The 5-year CIN 3+ risk is 0.51% after one negative HPV-based test and

decreases to 0.23% after the second negative test. Following the second negative test, patients qualify for a 3-year return for follow-up, and continued testing every 3 years is recommended due to the low number of CIN 3+ cases after multiple negative tests (p. 122).

For patients with histologic HSIL (CIN 2) who prioritize fertility preservation over treatment, observation or treatment is acceptable if the squamocolumnar junction is visible and CIN 2+ or ungraded CIN is not detected on endocervical sampling. For patients aged 25 and older, observation includes colposcopy and HPV-based testing every 6 months for up to 2 years. If evaluations show less than CIN 2 and less than ASC-H on two occasions, 6 months apart, follow-up should continue yearly. After three consecutive negative annual tests, long-term surveillance can begin. If CIN 2 persists for 2 years, treatment is recommended (p. 118).

For patients treated for high-grade histologic or cytologic abnormalities, after an initial HPV-based test at 6 months, annual testing should continue until three negative results are achieved. After this period, surveillance at 3-year intervals is recommended for at least 25 years, even beyond age 65 if the patient is in good health (p. 122).

For patients with cytology showing AGC-NOS or AEC-NOS without evidence of HSIL (CIN 2+), AIS, or cancer, co-testing is recommended at 1 and 2 years. If both tests are negative, repeat co-testing is recommended every 3 years (p. 113-114).

For patients aged 21 to 29 with negative cytology and absent endocervical or transformation zone cells, the guidelines recommend routine screening. HPV testing is not acceptable as a triage in this age group. For patients 30 years or older with NILM cytology and absent transformation zone cells, the guidelines prefer HPV testing, but if not performed, repeat cytology in 3 years is acceptable. If HPV testing is done, those with negative HPV results should return to routine screening and those found to be HPV positive should return for HPV-based testing in 1 year (p. 115).

For patients undergoing fertility-sparing management of adenocarcinoma in situ, follow-up involves co-testing and endocervical sampling every 6 months for at least 3 years, followed by annual testing for at least 2 years. If results remain consistently negative for 5 years, the surveillance interval can be extended to every 3 years. If abnormal cytology or positive HPV test results occur during surveillance, a hysterectomy is recommended after completion of childbearing (p. 121).

After a diagnosis of high-grade histology or cytology, patients who undergo a hysterectomy for treatment should have 3 consecutive annual HPV-based tests before transitioning to long-term surveillance. Long-term surveillance for histologic HSIL (CIN 2 or CIN 3) or AIS involves HPV-based testing every 3 years for 25 years, regardless of whether a hysterectomy was performed. For patients without a previous diagnosis of CIN 2+ in the past 25 years or who have completed the 25-year surveillance, screening is generally not recommended. If vaginal

screening is performed, abnormal results should be managed according to published recommendations (p. 125).

Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines: Updates Through 2023. J Low Genit Tract Dis. 2024;28(1):3-6. doi:10.1097/LGT.0000000000000788

Moscicki, et al.

In the 2019 guidelines titled "Guidelines for Cervical Cancer Screening in Immunosuppressed Women Without HIV Infection," a panel of expert authors proposed that cervical cancer screening for non-HIV immunocompromised women should follow either general population guidelines or CDC/NIH/HIVMA/IDSA guidelines for HIV-infected women, noting the following conditions:

- Solid Organ Transplant and Stem Cell Transplant: Higher risk of cervical cancer; follow guidelines for HIV-infected women.
- Inflammatory Bowel Disease: Women on immunosuppressive therapy have a higher risk and should follow HIV guidelines; those not on immunosuppressive therapy should follow general population guidelines.
- Systemic Lupus Erythematosus and Rheumatoid Arthritis: Women on immunosuppressive therapy have a higher risk and should follow HIV guidelines; those not on immunosuppressive therapy should follow general population guidelines (p. 87).

Moscicki AB, Flowers L, Huchko MJ, et al. Guidelines for Cervical Cancer Screening in Immunosuppressed Women Without HIV Infection. J Low Genit Tract Dis. 2019;23(2):87-101. doi:10.1097/LGT.0000000000000468

American College of Obstetricians and Gynecologists (ACOG)

In ACOG Practice Bulletin No. 215: Vaginitis in Nonpregnant Patients, the authors state: "Pap tests are not reliable for the diagnosis of vaginitis" (p. e10).

Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. Obstet Gynecol. 2020 Jan;135(1):e1-e17. PMID: 31856123. doi:10.1097/AOG.0000000000003604.

Multi-Cancer Early Detection Screening Tests

Wade, et al.

A 2025 systematic literature review examined 36 studies of the use of multi-cancer early detection tests which met inclusion criteria, including studies performed in US-based populations. The review concluded that the decision regarding whether or not to implement multi-cancer early detection tests on asymptomatic populations should be supported by robust evidence such as a randomized controlled trial, with an appropriate length of time for proper follow-up to ensure evidence-based evaluation. None of the tests evaluated by this systematic review were supported by this level of evidence, and therefore widespread use of multi-cancer early detection tests cannot be recommended at this time (p. 41).

Wade R, Nevitt S, Liu Y, et al. Multi-cancer early detection tests for general population screening: a systematic literature review. Health Technology Assessment. 2025 Jan;29(2):1–105. doi:10.3310/dlmt1294.

National Cancer Institute (NCI)

According to the NCI, there are no large clinical trials showing that the use of any MCD (multi-cancer detection) test for cancer screening reduces the number of individuals who die from cancer. To date, there are no professional medical societies, including the U.S. Preventive Services Task Force (USPSTF), that have issued recommendations on the use of MCD tests for cancer screening.

Multi-Cancer Detection (MCD) research. Division of Cancer Prevention. Accessed April 9, 2025. https://prevention.cancer.gov/major-programs/multi-cancer-detection-mcd-research.

DEFINITIONS

1. **Fecal immunohistochemical testing (FIT):** Screening test for colon cancer that detects human blood in the lower intestines. (FIT testing alone does not involve any genetic test and is outside of the scope of this policy).
2. **FIT-DNA testing:** Combination of the fecal immunochemical (FIT), which uses antibodies to detect blood in the stool, with a test that detects abnormal DNA from cancer or polyp cells in the stool.
3. **Close relatives** include first, second, and third degree blood relatives:
    a. **First-degree relatives** are parents, siblings, and children
    b. **Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings

c. **Third-degree relatives** are great grandparents, great aunts, great uncles, great grandchildren, and first cousins

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
80047	Basic metabolic panel (Calcium, ionized) This panel must include the following: Calcium, ionized (82330) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) Urea Nitrogen (BUN) (84520)
80048	Basic metabolic panel (Calcium, total) This panel must include the following: Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Potassium (84132) Sodium (84295) Urea nitrogen (BUN) (84520)
80050	General Health Panel
80051	Electrolyte panel This panel must include the following: Carbon dioxide (bicarbonate) (82374) Chloride (82435) Potassium (84132) Sodium (84295)
80053	Comprehensive metabolic panel This panel must include the following: Albumin (82040) Bilirubin, total (82247) Calcium, total (82310) Carbon dioxide (bicarbonate) (82374) Chloride (82435) Creatinine (82565) Glucose (82947) Phosphatase, alkaline (84075) Potassium (84132) Protein, total (84155) Sodium (84295) Transferase, alanine amino (ALT) (SGPT) (84460) Transferase, aspartate amino (AST) (SGOT) (84450) Urea nitrogen (BUN) (84520)
80061	Lipid panel This panel must include the following: Cholesterol, serum, total (82465) Lipoprotein, direct measurement, high density cholesterol (HDL cholesterol) (83718) Triglycerides (84478)
81000	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy

CPT® Codes	Description
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, without microscopy
81005	Urinalysis; qualitative or semiquantitative, except immunoassays
81007	Urinalysis; bacteriuria screen, except by culture or dipstick
81015	Urinalysis; microscopic only
81020	Urinalysis; 2 or 3 glass test
81099	Unlisted urinalysis procedure
82040	Albumin; serum, plasma or whole blood
82042	Albumin; other source, quantitative, each specimen
82270	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided 3 cards or single triple card for consecutive collection)
82271	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; other sources
82272	Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces, 1-3 simultaneous determinations, performed for other than colorectal neoplasm screening
82374	Carbon dioxide (bicarbonate)
82435	Chloride; blood
82436	Chloride; urine
82465	Cholesterol, serum or whole blood, total
82523	Collagen cross links, any method
82542	Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen
82550	Creatine kinase (CK), (CPK); total
82552	Creatine kinase (CK), (CPK); isoenzymes
82803	Gases, blood, any combination of pH, pCO2, pO2, CO2, HCO3 (including calculated O2 saturation);
82805	Gases, blood, any combination of pH, pCO2, pO2, CO2, HCO3 (including calculated O2 saturation); with O2 saturation, by direct measurement, except pulse oximetry

CPT® Codes	Description
82945	Glucose, body fluid, other than blood
82946	Glucagon tolerance test
82947	Glucose; quantitative, blood (except reagent strip)
82948	Glucose; blood, reagent strip
82950	Glucose; post glucose dose (includes glucose)
82951	Glucose; tolerance test (GTT), 3 specimens (includes glucose)
82952	Glucose; tolerance test, each additional beyond 3 specimens (List separately in addition to code for primary procedure)
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use
82985	Glycated protein
83036	Hemoglobin; glycosylated (A1C)
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use
83605	Lactate (lactic acid)
83615	Lactate dehydrogenase (LD), (LDH);
83625	Lactate dehydrogenase (LD), (LDH); isoenzymes, separation and quantitation
83690	Lipase
83700	Lipoprotein, blood; electrophoretic separation and quantitation
83701	Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (eg, electrophoresis, ultracentrifugation)
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83719	Lipoprotein, direct measurement; VLDL cholesterol
83721	Lipoprotein, direct measurement; LDL cholesterol
83722	Lipoprotein, direct measurement; small dense LDL cholesterol
83861	Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity
83872	Mucin, synovial fluid (Ropes test)
83874	Myoglobin
83876	Myeloperoxidase (MPO)
83930	Osmolality; blood

CPT® Codes	Description
83935	Osmolality; urine
83986	pH; body fluid, not otherwise specified
84075	Phosphatase, alkaline;
84080	Phosphatase, alkaline; isoenzymes
84100	Phosphorus inorganic (phosphate);
84105	Phosphorus inorganic (phosphate); urine
84134	Prealbumin
84155	Protein, total, except by refractometry; serum, plasma or whole blood
84156	Protein, total, except by refractometry; urine
84157	Protein, total, except by refractometry; other source (eg, synovial fluid, cerebrospinal fluid)
84160	Protein, total, by refractometry, any source
84165	Protein; electrophoretic fractionation and quantitation, serum
84166	Protein; electrophoretic fractionation and quantitation, other fluids with concentration (eg, urine, CSF)
84295	Sodium; serum, plasma or whole blood
84300	Sodium; urine
84478	Triglycerides
84520	Urea nitrogen; quantitative
84545	Urea nitrogen, clearance
84550	Uric acid; blood
84560	Uric acid; other source
84999	Unlisted chemistry procedure
85007	Blood count; blood smear, microscopic examination with manual differential WBC count
85013	Blood count; spun microhematocrit
85025	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) and automated differential WBC count
85027	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)
85045	Blood count; reticulocyte, automated
85651	Sedimentation rate, erythrocyte; non-automated
85652	Sedimentation rate, erythrocyte; automated
86140	C-reactive protein;
86141	C-reactive protein; high sensitivity (hsCRP)

CPT® Codes	Description
P9016	Blood unit, non-pheresis
P9037	Platelets, pheresis, CMV-negative
P9040	RBC, leukocytes reduced, irradiated

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	1/26	1/26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.
Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.