



UM-CDG-001 Tumor Markers

Approved By:
Director, Health Services

Effective Date:
10/31/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address tumor markers, including somatic (acquired) mutations in oncology.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

SECUR Health Plan considers any of the following tumor markers for the stated indication medically necessary, unless otherwise stated:

1. 1p19q codeletion molecular cytogenetic analysis for astrocytomas and gliomas;
2. 5-hydroxyindoleacetic acid (5-HIAA) for neuroendocrine tumors;
3. Afirma Thyroid FNA analysis for assessing fine needle aspiration samples from thyroid nodules that are indeterminate; experimental for other indications. Repeat testing is considered experimental, investigational, or unproven;
4. ALK expression for pancreatic adenocarcinoma, pediatric Hodgkin's lymphoma, inflammatory myofibroblastic tumor (IMT) with ALK translocation, breast implant-associated ALCL, peripheral T-cell lymphoma, and uterine sarcoma;
5. ALK gene fusion as a molecular biomarker in non-small cell lung cancer;
6. ALK gene rearrangement for diffuse large B cell lymphoma, anaplastic thyroid carcinoma, primary

cutaneous CD30+ T-cell lymphoproliferative disorders, post-transplant lymphoproliferative disorder, and non-small cell lung cancer;

7. Alpha fetoprotein (AFP) for testing for hepatocellular carcinoma in hepatitis B carriers, or for persons with cirrhosis and one or more of the following risk factors: alcohol use; alpha-1 antitrypsin deficiency; Asian female at least 50 years of age; Asian male at least 40 years of age; family history of HCC; genetic hemochromatosis; hepatitis C; nonalcoholic steatohepatitis; and stage 4 primary biliary cirrhosis;
8. Alpha fetoprotein (AFP) for the following indications: hepatocellular carcinoma; mediastinal mass; ovarian cancer; pelvic mass; testicular cancer; testicular mass; thymic carcinoma; and thymoma;
9. Alpha fetoprotein (AFP): serial measurements to diagnose germ cell tumors in members with adenocarcinoma, or carcinoma not otherwise specified, involving mediastinal nodes; or the diagnosis and monitoring of hepatocellular carcinoma (e.g., before considering liver transplantation);
10. Androgen receptor splice variant 7 (AR-V7) in circulating tumor cells to select therapy in metastatic castrate-resistant prostate cancer after progression on abiraterone or enzalutamide;
11. BCL2 and BCL6 for the diagnosis of non-Hodgkin's lymphoma and Castleman's disease;
12. BCR/ABL for acute lymphocytic leukemia (ALL), acute myeloid leukemia (AML), B-cell lymphoblastic lymphoma, chronic myelogenous leukemia (CML), and suspected myeloproliferative neoplasm; experimental, investigational, or unproven for other indications;
13. Beta-2 microglobulin (B2M) for multiple myeloma, non-Hodgkin's lymphoma and Waldenström's macroglobulinemia/ lymphoplasmacytic lymphoma;
14. BIRC3 and MALT1 for gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma;
15. BRAF V600 mutation for indeterminate thyroid nodules, hairy cell leukemia; gastrointestinal stromal tumors; colorectal cancer, Lynch syndrome; non-small cell lung cancer; thyroid carcinoma; infiltrative glioma, pancreatic adenocarcinoma, and melanoma or Lynch syndrome and colorectal cancer if KRAS nonmutated; experimental for other indications;
16. Breast Cancer Index (BCI) to assess necessity of adjuvant chemotherapy or adjuvant endocrine therapy in females or males with recently diagnosed breast tumors where all of the following criteria are met:
 - Breast cancer is nonmetastatic (node negative) or with 1-3 involved ipsilateral axillary lymph nodes; and
 - Breast tumor is estrogen receptor and/or progesterone receptor positive; *and*
 - Breast tumor is HER2 receptor negative; *and*
 - Adjuvant therapy is not precluded due to any other factor (e.g., advanced age and/or significant comorbidities); *and*
 - Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy;

BCI is also considered medically necessary for person with HER2-negative breast cancer with 0-3 positive nodes who received five (5) years of endocrine therapy without recurrence to guide decisions about extended endocrine therapy.

17. BTK (Bruton's tyrosine kinase) for chronic lymphocytic leukemia/small lymphocytic lymphoma;
18. CA 15-3: Serial measurements of CA 15-3 (also known as CA 27-29 or Truquant RIA) in following the course of treatment in women diagnosed with breast cancer, especially advanced metastatic breast cancer (an increasing CA 15-3 level may suggest treatment failure);
19. CA 19-9 for the following indications:
 - To monitor the clinical response to therapy or detect early recurrence of disease in members with known gastric cancer, pancreatic cancer, gallbladder cancer, cholangiocarcinoma, ovarian cancer, small bowel adenocarcinoma, or adenocarcinoma of the ampulla of Vater; *or*
 - To rule out cholangiocarcinoma in persons with primary sclerosing cholangitis undergoing liver transplantation; *or*
 - For evaluation of jaundice, abnormal liver function tests (LFTs) or hepatobiliary obstruction/abnormality on abdominal imaging; *or*
 - As a tumor marker for mucinous appendiceal carcinoma;
20. CALB2 (calretinin) expression for lung cancer and occult primary;
21. CALCA (calcitonin) expression for medullary thyroid cancer or for adenocarcinoma or anaplastic/undifferentiated tumors of the head and neck;
22. CALR (calreticulin) for chronic myeloid leukemia (chronic phase, adult), myelodysplastic syndrome, or myeloproliferative neoplasms;
23. Cancer antigen 125 (CA 125) levels for *any* of the following:
 - As a preoperative diagnostic aid in women with ovarian masses that are suspected to be malignant, such that arrangements can be made for intraoperative availability of a gynecological oncologist if the CA 125 is increased; *or*
 - As a screening test for ovarian cancer when there is a family history of hereditary ovarian cancer syndrome (a pattern of clusters of ovarian cancer within two or more generations), where testing is performed concurrently with transvaginal ultrasound and prophylactic salpingo-oophorectomy has not been performed. For this indication, screening is considered medically necessary every six months beginning at 30 years of age or 10 years before the earliest age of the first diagnosis of ovarian cancer in the family; *or*
 - Diagnosis of ovarian cancer in women with new symptoms (bloating, pelvic or abdominal pain, difficulty eating or feeling full quickly, or urinary frequency and urgency) that have persisted for three or more weeks, where the clinician has performed a pelvic and rectal examination and suspects ovarian cancer; *or*
 - In members with adenocarcinoma of unknown primary, to rule out ovarian cancer; *or*
 - In members with known ovarian cancer, as an aid in the monitoring of disease, response to

treatment, detection of recurrent disease, or assessing value of performing second-look surgery;

24. Carcinoembryonic antigen (CEA) for any of the following:

- As a preoperative prognostic indicator in members with known colorectal carcinoma or mucinous appendiceal carcinoma when it will assist in staging and surgical treatment planning; *or*
- Pancreatic cyst fluid CEA for distinguishing mucinous from non-mucinous malignant pancreatic cysts; *or*
- To detect asymptomatic recurrence of colorectal cancer after surgical and/or medical treatment for the diagnosis of colorectal cancer (not as a screening test for colorectal cancer); *or*
- To monitor response to treatment for metastatic colorectal cancer; *or*
- For cholangiocarcinoma, gallbladder cancer, lung cancer, medullary thyroid cancer, metastatic breast cancer, mucinous ovarian cancer, and occult primary; *or*
- For evaluation of jaundice, abnormal liver function tests (LFTs) or for obstruction/abnormality of the bile duct on liver imaging;

25. CFBF for acute myeloid leukemia;

26. CCND1 (cyclin D1) for B-cell lymphomas, primary cutaneous B-cell lymphomas, chronic lymphocytic leukemia/small lymphocytic lymphoma, and hairy cell leukemia;

27. CD 20, for determining eligibility for anti-CD20 treatment (rituximab)

28. CD 25, for determining eligibility for denileukin diftitox (Ontak) treatment;

29. CD 31 immunostaining, for diagnosis of angiosarcoma;

30. CD 33, for lymphoblastic lymphoma and for determining eligibility for anti-CD33 (gemtuzumab, Mylotarg) treatment;

31. CD 52, for post-transplant lymphoproliferative disorder, T-cell prolymphocytic leukemia, and for determining eligibility for anti-CD52 (alemtuzumab, Campath) treatment;

32. CD117 (c-kit), for acute myeloid leukemia, cutaneous melanoma, gastrointestinal stromal tumors and systemic mastocytosis;

33. CHGA (Chromogranin A) expression for neuroendocrine tumors, non-small cell lung cancer, small cell lung cancer, Merkel cell carcinoma and occult primary;

34. Copy number alterations molecular testing for pediatric diffuse high-grade glioma;

35. Decipher for the following indications:

- Post biopsy in men with NCCN very-low-risk, low-risk, and favorable intermediate-risk prostate cancer who have a greater than 10 year life expectancy who have not received treatment for prostate cancer and are candidates for active surveillance or definitive therapy; *or*
- Post biopsy in men with intermediate-risk prostate cancer when deciding whether to add androgen-

deprivation therapy to radiation; *or*

- Men with an undetectable PSA after prostatectomy for prostate cancer, to determine adjuvant versus salvage radiation therapy or to determine whether to initiate systemic therapies;

36. DecisionDx-UM (Castle Biosciences, Phoenix, AZ) for risk stratification of persons with localized uveal melanoma;

37. EndoPredict (also known as 12-gene score)Footnote2** to assess necessity of adjuvant chemotherapy in females or males with recently diagnosed breast tumors, where *all* of the following criteria are met:

- Breast cancer is nonmetastatic (node negative) or with 1-3 involved ipsilateral axillary lymph nodes; *and*
- Breast tumor is estrogen receptor positive; *and*
- Breast tumor is HER2 receptor negative; *and*
- Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); *and*
- Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy;

38. EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) for the workup of the following:

- Myelodysplastic syndrome (MDS), and
- Myeloproliferative neoplasms (MPN) to evaluate for higher-risk mutations associated with disease progression in members with primary myelofibrosis (PMF);

SECUR Health Plan considers EZH2 experimental, investigational, or unproven for all other indications including diffuse Large B-cell lymphomas;

39. FIP1L1-PDGFR fusion oncogene for systemic mastocytosis with peripheral blood eosinophilia;

40. FIP1L1-PDGFR gene rearrangements for myeloid/lymphoid neoplasms with peripheral blood eosinophilia and tyrosine kinase fusion genes;

41. FLT3 gene mutation testing for acute lymphoblastic leukemia, acute myeloid leukemia (AML), myelodysplastic syndromes, myeloproliferative neoplasms, and myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes;

42. Human chorionic gonadotropin (HCG), serial measurement to diagnose germ cell tumors in members with adenocarcinoma, or carcinoma not otherwise specified, involving mediastinal nodes, or to monitor treatment in members with known trophoblastic tumors (invasive hydatidiform moles and choriocarcinomas) and germinal cell tumors (teratocarcinoma and embryonal cell carcinoma) of the ovaries or testes, or to monitor for relapse after remission is achieved;

43. Human chorionic gonadotropin, beta (beta-HCG) for mediastinal mass; ovarian cancer; pelvic mass; testicular mass; testicular cancer; thymoma; or thymic carcinoma;
44. Human epidermal growth factor receptor 2 (HER2) (ERBB2) evaluation in biliary tract, bladder, breast, cervical, colorectal, esophageal, esophageal gastric junction, gastric, non-small cell lung cancer (NSCLC), ovarian/fallopian tube, and salivary gland tumors.
45. Human papillomavirus (HPV) tumor testing (p16) for the workup of head and neck cancer (including oropharynx cancer) or occult primary cancers;
46. IGH@ (Immunoglobulin heavy chain locus), gene rearrangement analysis to detect abnormal clonal population(s) in non-Hodgkin's lymphomas, chronic lymphocytic leukemia, hairy cell leukemia, and post-transplant lymphoproliferative disorder;
47. IGK@ (Immunoglobulin kappa light chain locus), gene rearrangement analysis, evaluation to detect abnormal clonal population(s) for non-Hodgkin's lymphoma, systemic light chain amyloidosis;
48. INHA (inhibin) expression for ovarian cancer or pelvic mass;
49. Isocitrate dehydrogenase 1 and 2 (IDH1 and IDH2) gene mutation for AML, chondrosarcomas, myelodysplastic syndromes, myeloproliferative neoplasms, or gliomas and glioblastomas;
50. KRAS for metastatic colorectal cancer, myelodysplastic syndromes, non-small cell lung cancer, pancreatic adenocarcinoma, and uterine sarcoma;
51. Lactate dehydrogenase (LDH) for acute lymphoblastic leukemia (ALL), bone cancer, kidney cancer, kidney mass, lung cancer, multiple myeloma, non-Hodgkin's lymphoma, pelvic mass, ovarian cancer, testicular cancer, or testicular mass;
52. Liquid biopsy (up to 50 genes) (e.g., Resolution ctDx Lung, InVisionFirst-Lung) for persons with non-small cell lung cancer who are not medically fit for invasive sampling, or there is insufficient tissue for molecular analysis and follow-up tissue-based analysis will be done if an oncogenic driver is not identified; large liquid biopsy panels (greater than 50 genes) are considered experimental, investigational, or unproven for non-small cell lung cancer; for Guardant360CDx non-small cell lung cancer and FoundationOne Liquid CDx for non-small cell lung cancer and prostate cancer;
53. MammaPrint to assess necessity of adjuvant chemotherapy in females or males with recently diagnosed breast tumors where all of the following criteria are met:
 - Breast cancer is nonmetastatic (node negative^{Footnote1*}) or with 1-3 involved ipsilateral axillary lymph nodes; *and*
 - Breast tumor is estrogen receptor positive or progesterone receptor positive; *and*
 - Breast tumor is HER2 receptor negative (Rationale: adjuvant chemotherapy with trastuzumab (Herceptin) is considered to be medically necessary regardless of MammaPrint score for HER2 receptor positive lesions); *and*
 - Member is determined to be at "high clinical risk" of recurrence using Adjuvant! Online; *and*

- Adjuvant chemotherapy is not precluded due to any other factor; *and*
 - Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy;
54. Measurement of estrogen receptors (ESR1) for breast cancer, endometrial carcinoma, non-small cell lung cancer, occult primary, ovarian cancer, or uterine sarcoma;
55. Measurement of progesterone receptors (PGR) for breast cancer, non-small cell lung cancer, occult primary, or uterine sarcoma;
56. Microsatellite instability (MSI) molecular testing for *any* of the following indications:
- Adrenal gland tumor (including adrenocortical carcinoma)
 - Biliary tract cancers (i.e., extrahepatic cholangiocarcinoma, gallbladder cancer, intrahepatic cholangiocarcinoma)
 - Bone cancer (i.e., chondrosarcoma, chordoma, Ewing sarcoma, osteosarcoma)
 - Breast cancer (invasive)
 - Cervical cancer
 - Colon cancer (including appendiceal adenocarcinoma)
 - Esophageal and esophagogastric junction cancers
 - Gastric cancer
 - Head and neck cancer (including salivary gland tumors)
 - Lynch syndrome
 - Neuroendocrine (i.e., extrapulmonary poorly differentiated neuroendocrine carcinoma / large or small cell carcinoma / mixed neuroendocrine-non-neuroendocrine neoplasm)
 - Occult primary
 - Ovarian cancer / fallopian tube cancer / primary peritoneal cancer (including epithelial ovarian cancer, and less common ovarian cancers [e.g., grade 1 endometrioid carcinoma])
 - Penile cancer
 - Prostate cancer
 - Rectal cancer
 - Small bowel adenocarcinoma
 - Testicular Cancer (including nonseminoma, seminoma)
 - Thyroid carcinoma (i.e., anaplastic, follicular, oncocyctic, papillary)
 - Upper genitourinary tract (GU) tract tumors
 - Uterine neoplasms (i.e., endometrial carcinoma, uterine sarcoma)
 - Vulvar cancer - squamous cell carcinoma;
57. Mismatch repair (MSI/dMMR) (MLH1, MSH2, MSH6, PMS2) tumor testing (somatic mutations) for breast cancer, ovarian cancer, colorectal cancer, small bowel adenocarcinoma, esophageal cancer, esophagogastric junction cancer, gastric cancer, pancreatic cancer, cholangiocarcinoma, gallbladder cancer, pancreatic adenocarcinoma, cervical cancer, uterine cancer, prostate cancer, testicular cancer, penile cancer, myelodysplastic syndromes, Ewing sarcoma, and occult primary;
58. MLH1 tumor promoter hypermethylation for endometrial cancer;

59. MPL (myeloproliferative leukemia protein) for chronic myeloid leukemia (chronic phase, adult), myelodysplastic syndromes, or myeloproliferative neoplasms;
60. Murine double minute 2 (MDM2) for uterine sarcoma and soft tissue sarcoma;
61. Mycosis fungoides, diagnosis: polymerase chain reaction (PCR) for T-cell receptor gamma chain gene rearrangement as an adjunct to the histopathologic diagnosis of mycosis fungoides;
62. MYD88 (myeloid differentiation primary response 88) to differentiate Waldenstrom's macroglobinemia (WM) versus marginal zone lymphoma (MZL) if plasmacytic differentiation present for gastric MALT lymphoma, nodal marginal zone lymphoma, nongastric MALT lymphoma, and splenic marginal zone lymphoma; and for multiple myeloma;
63. Myeloperoxidase (MPO) immunostaining, CEBPA mutation, and KIT mutation for diagnosis of acute myeloid leukemia;
64. MyMRD NGS Panel for comprehensive prognostic assessment in individuals with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS);
65. Next generation sequencing of tumor DNA (e.g., ClonoSeq) to detect or quantify minimal residual disease in persons with multiple myeloma or acute lymphocytic leukemia;
66. NPM1 in acute myeloid leukemia (AML), chronic myeloid leukemia (chronic phase, adult), myelodysplastic syndromes, or myeloproliferative neoplasms; experimental for other indications;
67. NRAS for colorectal cancer, myelodysplastic syndrome, or blastic plasmacytoid dendritic cell neoplasm (BPDCN);
68. NTRK for all solid tumors;
69. Oncotype Dx Breast (also known as 21 gene RT-PCR test) to assess necessity of adjuvant chemotherapy in females or males with recently diagnosed breast tumors, where *all* of the following criteria are met:
 - Breast cancer is nonmetastatic (node negative) or with 1-3 involved ipsilateral axillary lymph nodes; *and*
 - Breast tumor is estrogen receptor positive; *and*
 - Breast tumor is HER2 receptor negative or breast tumor is HER2 receptor positive and less than 1 cm in diameter. (Rationale: adjuvant chemotherapy with trastuzumab (Herceptin) is considered to be medically necessary regardless of an Oncotype Dx Breast score for HER2 receptor positive lesions 1 cm or more in diameter); *and*
 - Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); *and*
 - Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy (i.e., member will forgo adjuvant chemotherapy if Oncotype Dx Breast score is low);
70. Oncotype DX Prostate for the following indications post biopsy:

- Men with NCCN very-low-risk, low-risk, and favorable intermediate-risk prostate cancer who have greater than 10 year life expectancy and who have not received treatment for prostate cancer and are candidates for active surveillance or definitive therapy, or
 - Men with intermediate-risk prostate cancer when deciding whether to add androgen-deprivation therapy to radiation
71. PAM50 Risk of Recurrence (ROR) Score (also known as Prosigna Breast Cancer Prognostic Gene Signature Assay) to assess necessity of adjuvant chemotherapy in females or males with recently diagnosed breast tumors, where *all* of the following criteria are met:
- Breast cancer is nonmetastatic (node negative), and
 - Breast tumor is estrogen receptor positive, and
 - Breast tumor is HER2 receptor negative, and
 - Adjuvant chemotherapy is not precluded due to any other factor, and
 - Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy
72. PDGFRA for gastrointestinal stromal tumors (GIST) and for pediatric acute lymphoblastic leukemia (see also entry above for FIP1L1-PDGFR gene rearrangements and fusions);
73. PDGFRB testing for myelodysplastic syndromes (MDS), dermatofibrosarcoma protuberans, acute lymphoblastic leukemia, and for myeloid/lymphoid neoplasms with peripheral blood eosinophilia and tyrosine kinase fusion genes;
74. Phosphatidylinositol-4,5-bisphosphonate 3-kinase, catalytic subunit alpha polypeptide gene (PIK3CA) for breast cancer and uterine sarcoma;
75. Placental alkaline phosphatase (PLAP), to diagnose germ cell seminoma and non-seminoma germ cell tumors in unknown primary cancers;
76. PLCG2 (phospholipase C gamma 2) for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL);
77. PML/RARA for acute promyelocytic leukemia; experimental for all other indications;
78. Predicting response to EGFR-targeting tyrosine kinase inhibitors in non-small cell lung cancer (NSCLC); KRAS mutation testing to predict non-response to treatment of anal adenocarcinoma, metastatic colorectal cancer, NSCLC, and small bowel adenocarcinoma; or ROS-1 to predict response to treatment of NSCLC,
79. Prolaris for the following indications post biopsy
- Men with NCCN very-low-risk and favorable intermediate-risk prostate cancer who have greater than 10 year life expectancy and who have not received treatment for prostate cancer and are candidates for active surveillance or definitive therapy, or
 - Men with intermediate-risk prostate cancer when deciding whether to add androgen-deprivation therapy to radiation

80. ProMark for the following indications post biopsy:
- Men with NCCN very-low-risk and favorable intermediate-risk prostate cancer who have greater than 10 year life expectancy and who have not received treatment for prostate cancer and are candidates for active surveillance or definitive therapy, or
 - Men with intermediate-risk prostate cancer when deciding whether to add androgen-deprivation therapy to radiation
81. Prostate-specific antigen (PSA) for prostate cancer screening, staging, monitoring response to therapy, and detecting disease recurrence;
82. PTEN for uterine sarcoma and for persons meeting Cowden syndrome testing criteria; experimental for all other indications;
83. Quest Diagnostics Thyroid Cancer Mutation Panel for assessing fine needle aspiration samples from thyroid nodules that are indeterminate; experimental for other indications. Repeat testing is considered experimental, investigational, or unproven;
84. RUNX1 for acute myeloid leukemia, myelodysplastic syndrome, and systemic mastocytosis;
85. SF3B1 (splicing factor 3b subunit 1) for chronic myeloid leukemia (chronic phase, adult), myelodysplastic syndromes, myeloproliferative neoplasms, or uveal melanoma;
86. SRSF2 (serine and arginine rich splicing factor 2) for chronic myeloid leukemia (chronic phase, adult), myelodysplastic syndromes, myeloproliferative neoplasms, or systemic mastocytosis;
87. Steroid hormone receptor status in both pre-menopausal and post-menopausal members to identify individuals most likely to benefit from endocrine forms of adjuvant therapy and therapy for recurrent or metastatic breast cancer;
88. Targeted hematologic genomic sequencing panel (5-50 genes) for acute lymphocytic leukemia, acute myeloid leukemia, chronic myelogenous leukemia, myelodysplastic syndromes (MDS) and myeloproliferative neoplasms (MPN) (e.g., MedFusion myeloid malignancy analysis panel). Repeating a hematologic malignancy genomic sequencing panel within 60 days of prior panel testing for the same indication is considered not medically necessary;
89. Targeted solid organ genomic sequencing panel (5-50 genes) for colorectal cancer, cutaneous melanoma, pancreatic cancer, prostate cancer and non-small cell lung cancer (including Oncomine Dx Target Test (Thermo Fisher Scientific, Carlsbad, CA)). Repeating a solid organ malignancy genomic sequencing panel within 60 days of prior panel testing for the same indication is considered not medically necessary;
90. T-cell receptor gene rearrangements (TRA@, TRB@, TRD@, TRG@) for T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, nasal type extranodal NK/T-cell lymphoma, hepatosplenic gamma-delta T-cell lymphoma, peripheral T-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders, myelodysplastic syndromes, Castleman's disease, mycosis fungoides/Sezary syndrome and myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes;

91. TERT (telomerase reverse transcriptase) medically necessary for the workup of:
- Gliomas and
 - Myelodysplastic syndrome (MDS)
- SECUR Health Plan considers TERT experimental, investigational or unproven for all other indications including thyroid carcinoma.
92. ThyGeNEXT Thyroid Oncogene Panel (formerly e.g., ThyGenX, miRInform thyroid test) and ThyraMIR microRNA Classifier for assessing fine needle aspiration samples from thyroid nodules that are indeterminate; experimental for other indications; repeat testing is considered experimental, investigational, or unproven;
93. Thymidine kinase for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL);
94. Thyroglobulin antibodies for thyroid cancer;
95. Thyroglobulin (TG) expression for thyroid cancer, occult primary, and adenocarcinoma or anaplastic/undifferentiated tumors of the head and neck
96. Thyroid transcription factor-1 (TTF-1) for lung cancer or neuroendocrine tumors;
97. Thyroseq for assessing fine needle aspiration samples from thyroid nodules that are indeterminate; experimental for other indications. Repeat testing is considered experimental, investigational, or unproven;
98. TP53 for acute myeloid leukemia; adult medulloblastoma; chronic lymphocytic leukemia/small lymphocytic lymphoma; chronic myeloid leukemia (chronic phase, adult); endometrial carcinoma; malignant peritoneal or pleural mesothelioma; mantle cell lymphoma; myelodysplastic syndromes; myeloproliferative neoplasms; occult primary; pediatric acute lymphoblastic leukemia; peripheral T-cell lymphomas; splenic marginal zone lymphoma; uterine sarcoma; or well-differentiated, grade 3 neuroendocrine tumors;
99. Tumor mutation burden (TMB) molecular testing for testicular cancer (nonseminoma, seminoma);
100. U2AF1 (U2 small nuclear RNA auxiliary factor 1) for blastic plasmacytoid dendritic cell neoplasm (BPDCN), chronic myeloid leukemia (chronic phase, adult), myelodysplastic syndromes, or myeloproliferative neoplasms;
101. Urokinase plasminogen activator (uPA) and plasminogen activator inhibitor 1 to assess necessity of adjuvant chemotherapy in females or males with recently diagnosed breast tumors, where *all* of the following criteria are met:
- Breast cancer is nonmetastatic (node negative), and
 - Breast tumor is estrogen receptor positive, and
 - Breast tumor is HER2 receptor negative, and
 - Adjuvant chemotherapy is not precluded due to any other factor, and

- Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy

In addition, urokinase plasminogen activator (uPA) and plasminogen activator inhibitor (PAI-1) is considered medically necessary for the determination of prognosis in persons with newly diagnosed node negative breast cancer.

102. Vascular endothelial growth factor (VEGF) expression for Castleman's disease;
103. Veristat proteomic testing for members with advanced NSCLC, whose tumors were without EGFR and anaplastic lymphoma kinase (ALK) mutations, who had progressed after at least one chemotherapy regimen), and for whom erlotinib was considered an appropriate treatment;
104. WT-1 gene expression for desmoplastic round cell tumors, ovarian clear cell carcinomas, non-small cell lung cancer and occult primary;
105. ZAP-70, for assessing prognosis and need for aggressive therapy in persons with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL);
106. ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine rich 2) for chronic myeloid leukemia (chronic phase, adult) or myelodysplastic syndromes.

SECUR Health Plan considers somatic genomic testing for Janus Kinase 2 (JAK2) mutations in persons with chronic myeloproliferative disorders (CMPDs) medically necessary for the following indications:

- Qualitative assessment of JAK2-V617F sequence variant using methods with detection thresholds of up to 5% for initial diagnostic assessment of adult members presenting with symptoms of CMPD;
- Diagnostic assessment of polycythemia vera in adults, and
- Differential diagnosis of essential thrombocytosis and primary myelofibrosis from reactive conditions in adults

SECUR Health Plan considers somatic genomic testing for Janus Kinase 2 (JAK2) mutations in persons with chronic myeloproliferative disorders (CMPDs) experimental, investigational, or unproven for any other indication including:

- Quantitative assessment of JAK2-V617F allele burden subsequent to qualitative detection of JAK2-V617F

SECUR Health Plan considers ImmunoCyte/uCyt immunohistochemistry test experimental, investigational, or unproven in the evaluation of hematuria, diagnosing bladder cancer, or for screening for bladder cancer in asymptomatic persons.

SECUR Health Plan considers matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS or MASS-FIX) and immunoprecipitation for detection and isotyping of immunoglobulin paraprotein (M-protein) medically necessary for the evaluation and management of plasma cell dyscrasias.

SECUR Health Plan considers urinary biomarkers (e.g., bladder tumor antigen (BTA) (e.g., BTA Stat and BTA TRAK), nuclear matrix protein (NMP22) test, the fibrin/fibrinogen degradation products (Aura-Tek FDfP) test, or fluorescence in situ hybridization (FISH) (e.g., Pathnostics Bladder FISH test, UroVysion Bladder Cancer test) medically necessary in *any* of the following conditions:

- Follow-up of treatment for bladder cancer; *or*
- Monitoring for eradication of bladder cancer; *or*
- Recurrences after eradication.

SECUR Health Plan considers the BTA Stat test, the NMP22 test, the Aura-Tek FDP test, or the UroVysion fluorescent in situ hybridization (FISH) test experimental, investigational, or unproven for screening of bladder cancer, evaluation of hematuria, and diagnosing bladder cancer in symptomatic individuals, and all other indications.

Either standard node dissection negative by hematoxylin and eosin (H&E) staining or sentinel node negative by H&E staining (if sentinel node is negative by H&E, but immunoassay is positive, then still considered node negative for this purpose). In addition, women with isolated tumor cells in lymph nodes (micrometastases) are considered node negative.

More than one Oncotype Dx test may be medically necessary for persons with breast cancer who have two or more histologically distinct tumors that meet medical necessity criteria. Repeat Oncotype Dx testing or testing of multiple tumor sites in the same person has no proven value for other indications. Oncotype Dx is considered experimental, investigational, or unproven for ductal carcinoma in situ (OncotypeDx DCIS), colon cancer (OncotypeDx Colon), and all other indications other than breast cancer and prostate cancer.

SECUR Health Plan considers use of more than one type of test to determine necessity of adjuvant therapy in breast cancer (Oncotype Dx Breast, Breast Cancer Index, EndoPredict, PAM50, MammaPrint, or uPA and PAI-1) experimental, investigational, or unproven.

SECUR Health Plan considers repeat testing or use of more than one type of test to assess risk of prostate cancer progression (Oncotype Dx Prostate, Decipher, Prolaris, or ProMark) experimental, investigational, or unproven.

SECUR Health Plan considers each of the following experimental, investigational, or unproven. The peer-reviewed medical literature does not support these tests as having sufficient sensitivity or specificity necessary to define their clinical role:

- 3D Predict Ovarian Doublet Panel
- 3D Predict Ovarian PARP Panel
- 4Kscore
- Afirma Xpression Atlas
- AFP for the diagnosis of trophoblastic tumors and oncologic indications other than those listed in Section I
- AMBLor Melanoma Prognostic Test

- ArteraAI Prostate Test
- Assaying for loss of heterozygosity (LOH) on the long arm of chromosome 18 (18q) or deleted in colon cancer (DCC) protein (18q-LOH/DCC) for colorectal cancer
- Augusta Hematology Optical Genome Mapping
- Auria for breast cancer screening
- Avantect Pancreatic Cancer test
- Aventa FusionPlus
- BBDRisk Dx
- Biodesix BDX-XL2, Nodify CDT, Nodify Lung, or Nodify XL2 test for distinguishing benign from malignant lung nodules
- Biomarker Translation (BT) test for breast cancer and other indications
- BioSpeciFx, including Comprehensive Tumor Profiling for any indication
- BostonGene Tumor Portrait Test
- BRAF and EGFR for esophageal carcinoma
- Breast Cancer Gene Expression Ratio (HOXB13:IL17BR)
- BreastSentry
- BTG Early Detection of Pancreatic Cancer
- CA 125 for all other indications including use as a screening test for colorectal cancer or ovarian cancer (other than as indicated in Section I) or for differential diagnosis of members with symptoms of colonic disease
- CA 19-9 for all other indications not listed in Section I. including breast, colorectal, esophageal, gastro-esophageal, liver, or uterine cancer; ovarian cyst, NUT midline carcinoma of the nasal cavity, prediction of prognosis or treatment effect in persons with bladder (urothelial) cancer, screening persons with primary sclerosing cholangitis without signs or symptoms of cholangiocarcinoma; or screening persons with primary sclerosing cholangitis for development of cholangiocarcinoma
- Carcinoembryonic antigen cell adhesion molecule 6 (CEACAM6) (e.g., Benign Diagnostics Risk Test) for breast atypical hyperplasia and for predicting the risk of breast cancer
- Carcinoembryonic antigen cellular adhesion molecule-7 (CEACAM-7) expression as a predictive marker for rectal cancer recurrence
- Caris Molecular Intelligence/Caris Target Now Molecular Profiling Test
- Castle Biosciences myPath Melanoma (formerly Myriad myPath Melanoma)
- CDH1 for ovarian cancer
- CDX2 as a prognostic biomarker for colon cancer
- CEA used for all other indications not noted in Section I including *any* of the following:
 - i. As a screening test for colorectal cancer, or
 - ii. As a sole determinant to treat a colorectal cancer member with adjuvant therapy or systemic therapy for presumed metastatic disease, or
 - iii. For diagnosis of esophageal carcinoma, or
 - iv. For screening diagnosis, staging, or routine surveillance of gastric cancer.
- Circulating cell-free nucleic acids in colorectal cancer
- Circulating tumor cell (CTC) assays for all indications, including, but not limited to metastatic breast, colorectal, melanoma, and prostate cancers. Below includes CTC assays considered experimental, investigational, or unproven (not an all-inclusive list):
 - i. CellMax Life
 - ii. CELLSEARCH Circulation Multiple Myeloma Cell (CMMC)

- iii. CELLSEARCH HER2 Circulating Tumor Cell (CTC-HER2)
- iv. FirstSightCRC
- Circulating tumor DNA (ctDNA) (also referred to as a liquid biopsy) for any indication (other than small panels, less than 50 genes, for non-small cell lung cancer), including, but not limited to, colorectal cancer, melanoma, ovarian cancer or prostate cancer. Note: for EGFR liquid biopsy for non-small cell lung cancer (e.g., cobas EGFR Mutation Test v2), PIK3CA testing (therascreen PIK3CA RGQ PCR Kit) for breast cancer, ESR1 gene mutations (e.g., Guardant360 CDx assay) for breast cancer, and for other ctDNA/liquid biopsy testing in predicting response in members undergoing immunotherapy or targeted treatment. Below includes ctDNA/liquid biopsy tests considered experimental, investigational, or unproven (not an all-inclusive list):
 - i. CancerIntercept
 - ii. Colvera
 - iii. DefineMBC Epic Sciences ctDNA metastatic breast cancer panel
 - iv. GeneStrat
 - v. FoundationACT
 - vi. FoundationOne Liquid
 - vii. Guardant Reveal minimal residual disease (MRD) assessment and monitoring in breast, colorectal, and lung cancers
 - viii. Guardant360
 - ix. HPV-SEQ for monitoring disease burden in HPV-related cancers
 - x. LiquidHALLMARK
 - xi. Neolab Prostate
- CK5, CK14, p63, and Racemase P504S testing for prostate cancer
- c-Met expression for predicting prognosis in persons with advanced NSCLC and colorectal cancer, and other indications
- Cyfra21-1 (a cytokeratin 19 fragment), p53, squamous cell carcinoma antigen (SCC-Ag) and vascular endothelial growth factor C (VEGF-C) for diagnosis of esophageal carcinoma
- Cofilin (CFL1) as a prognostic and drug resistance marker in non-small cell lung cancer
- ColonSentry test for screening of colorectal cancer
- ColoPrint, CIMP, LINE-1 hypomethylation, and Immune cells for colon cancer
- Colorectal Cancer DSA (Almac Diagnostics, Craigavon, UK)
- ColoScape Test
- ConfirmMDx for prostate cancer
- Cxbladder tests (e.g., Cxbladder Triage, Cxbladder Detect+) for bladder cancer
- Cyclin D1 and FADD (Fas-associated protein with death domain) for head and neck squamous cell carcinoma
- CyPath Lung
- DAWN IO Melanoma
- DCIS Recurrence Score
- DCISionRT
- Decipher Bladder
- DecisionDx DiffDx-Melanoma (Castle Biosciences, Phoenix, AZ)
- DecisionDx-Melanoma (Castle Biosciences, Phoenix, AZ)
- DecisionDx-SCC (Castle Biosciences, Phoenix, AZ)

- Des-gamma-carboxy prothrombin (DCP) (also known as "prothrombin produced by vitamin K absence or antagonism II" [PIVKA II]) for diagnosing and monitoring hepatocellular carcinoma (HCC) and other indications
- DetermaRx
- DiviTum TKA test
- *Early*CDT-Lung test
- EarlyTect Bladder Cancer Detection (EarlyTect BCD)
- EGFR gene expression analysis for transitional (urothelial) cell cancer
- EGFRVIII for glioblastoma multiforme
- EML4-ALK as a diagnostic tool for stage IV non-small-cell lung cancer
- Endeavor Comprehensive Genomic Profiling
- Envisia Genomic Classifier
- Excision repair cross-complementation group 1 protein (ERCC1) for persons with NSCLC, colon or with gastric cancer who are being considered for treatment with platinum-based chemotherapy, and other indications
- ExoDx Prostate/ExosomeDx Prostate (IntelliScore)
- Fibrin/fibrinogen degradation products (FDP) test (e.g., DR-70 or Onko-Sure) for colorectal cancer
- FoundationOne, FoundationOne CDx and FoundationOne Heme (except where FoundationOne CDx is used as a companion diagnostic test for somatic/tumor BRCA testing)
- Galectin-3 for breast cancer, myelodysplastic syndrome, osteosarcoma, ovarian cancer, pancreatic cancer, and prostate cancer
- Gene hypermethylation for prostate cancer
- GeneKey (GeneKey Corp., Boston, MA)
- GeneSearch Breast Lymph Node (BLN) assay
- Glutathione-S-transferase P1 (GSTP1) for screening, detection and management of prostate cancer
- Grail Galleri Test
- Guanylyl cyclase c (GCC or GUCY2C) (e.g., Previstage GCC Colorectal Cancer State Test) for colorectal cancer
- Guardant360 TissueNext
- HelioLiver Test
- HeproDx
- HER2 testing of appendiceal cancer
- HERmark testing for breast cancer and other indications
- HMGB1 and RAGE in cutaneous malignancy (e.g., basal cell carcinoma, melanoma, and squamous cell carcinoma)
- Human epididymis protein 4 (HE4) (e.g., Elecsys HE4 assay) for endometrial cancer, ovarian cancer, or evaluation of pelvic mass, including to assist in the determination of referral for surgery to a gynecologic oncologist or general surgery, and for other indications
- IHC4 (e.g., NexCourse IHC4 by AQUA Technology) for breast cancer
- IMMray PanCan-d for detecting pancreatic ductal adenocarcinoma
- Immunoassay using magnetic nanosensor for diagnosis of lung cancer
- Immunoscore for estimating risk of recurrence or determining adjuvant therapy in persons with colon cancer
- Insight DX Breast Cancer Profile
- Insight TNBCtype

- Invitae PCM MRD Monitoring test
- Invitae PCM Tissue Profiling and MRD Baseline Assay
- IsoPSA
- Ki67 for breast cancer
- Ki-67 in upper tract urinary carcinoma
- Lectin-reactive alpha-fetoprotein (AFP-L3) for liver cancer
- Long non-coding RNA in gallbladder cancer
- LungLB and LungLife AI
- LungOI
- Lymph2CX and Lymph3Cx Lymphoma Molecular Classification Assay to distinguish between primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL)
- Mammostrat
- Mass spectrometry-based proteomic profiling for indeterminate pulmonary nodules
- MatePair targeted rearrangements (whole genome next-generation sequencing) for hematolymphoid neoplasia and solid organ neoplasia
- Mayo Clinic Laboratories Urinary Steroid Profile for the management of adrenal malignancies
- MelaNodal Predict for the management of cutaneous melanoma
- Merkel SmT Oncoprotein Antibody Titer
- Merkel Virus VP1 Capsid Antibody
- MI Cancer Seek
- Microarray-based gene expression profile testing using the MyPRS test for multiple myeloma
- Micro-RNAs (miRNAs) miRview mets and miRview mets2 (Rosetta Genomics Laboratories, Philadelphia, PA; Rosetta Genomics Ltd., Rehovot, Israel)
- M-inSight Patient Definition Assay
- M-inSight Patient Follow-Up Assessment
- miR-31now
- miR Sentinel Prostate Cancer Test
- Molecular Intelligence Services, including MI Profile and MI Profile X (formerly Target Now Molecular Profiling Test, including Target Now Select and Target Now Comprehensive)
- Molecular subtyping profile (e.g., BluePrint) for breast cancer
- mRNA gene expression profiling for cutaneous melanoma
- mRNA sequence analysis
- MSK-IMPACT
- MUC1 in gastric cancer
- Mucin 4 expression as a predictor of survival in colorectal cancer
- Mucin 5AC (MUC5AC) as serum marker for biliary tract cancer
- My Prognostic Risk Signature (MyPRS) (Signal Genetics LLC, New York, NY)
- MyAML Next Generation Sequencing Panel
- MyProstateScore (formerly Mi-Prostate Score [MiPS]), an assay of TMPRSS2:ERG (T2:ERG) gene fusion, post-DRE urine expression of PCA3, and serum PSA (KLK3)
- MyProstateScore 2.0
- NantHealth GPS Cancer Panels
- NavDx for surveillance of cancer recurrence in HPV-associated oropharyngeal cancer
- NETest
- NF1, RET, and SDHB for ovarian cancer

- NRAS mutation for selecting persons with metastatic colorectal cancer who may benefit from anti-VEGF antibody bevacizumab; to predict disease prognosis and select persons with melanoma who may benefit from tyrosine kinase inhibitor therapies, and other indications
- OmniSeq Advance DNA and RNA sequencing (OmniSeq and LabCorp)
- OneInsights (Intervention Insights, Grand Rapids, MI)
- OncobiotaLUNG
- Oncomap ExTra (formerly known as Oncotype MAP)
- OncoOmicDx Targeted Proteomic Assay
- OncoSignal test for analysis of solid tumors
- OncoTarget/OncoTreat
- Oncotype MAP PanCancer Tissue Test
- OncoVantage
- Oncuria Detect, Oncuria Monitor and Oncuria Predict for bladder cancer and all other indications
- OVA1/Overa test
- OvaCheck test
- OvaSure
- OvaWatch
- PancreaSeq Genomic Classifier
- PanGIA Prostate for determining if an individual should undergo a prostate biopsy
- Pathwork Tissue of Origin Test/ResponseDx Tissue of Origin Test
- Percepta Bronchial Genomic Classifier
- PGDx elio tissue complete (Personal Genome Diagnostics, Inc.) for tumor mutation profiling
- Pharmaco-oncologic AlgorithmicTreatment Ranking Service
- Phosphatidylinositol-4,5-bisphosphonate 3-kinase, catalytic subunit alpha polypeptide gene (PIK3CA) for predicting disease prognosis and selecting individuals with metastatic colorectal cancer who are being considered for treatment with EGFR antagonists cetuximab and panitumumab, and indications other than breast cancer and uterine sarcoma
- PLCG2 (phospholipase C gamma 2) for all indications other than chronic lymphocytic leukemia (CLL)
- Praxis Somatic Combined Whole Genome Sequencing and Optical Genome Mapping
- Praxis Somatic Optical Genome Mapping
- Praxis Somatic Transcriptome
- Praxis Somatic Whole Genome Sequencing
- PreciseDx Breast Cancer Test
- PreOvar test for the KRAS-variant to determine ovarian cancer risk
- ProOnc TumorSourceDx test (Prometheus Laboratories, San Diego, CA) to identify tissue or origin for metastatic tumor
- PROphet NSCLC test
- Prostate core mitotic test
- Prostate Px and Post-Op Px for predicting recurrence of prostate cancer
- Prostate Cancer Risk Panel (FISH analysis by Mayo Clinic)
- Proveri prostate cancer assay (PPCA)
- PSA for screening women with breast cancer or for differentiating benign from malignant breast masses
- PTEN gene expression for non-small cell lung cancer
- RadTox cfDNA test
- Ras oncogenes (except KRAS, NRAS and BRAF)

- ResponseDx Colon
- Ribonucleotide reductase subunit M1 (RRM1) for persons with NSCLC who are being considered for treatment with gemcitabine-based chemotherapy, and other indications
- RNA gene expression profiling for hematolymphoid disorder or neoplasm
- RNA gene expression for solid organ neoplasm
- ROMA (Risk of Ovarian Malignancy Algorithm) for ovarian cancer
- Rotterdam Signature 76-gene panel
- Salivary metatranscriptome analysis for oral cancers (i.e., mRNA CancerDetect)
- SelectMDx for prostate cancer
- Sentinel Prostate Test for prostate cancer screening and determining the risk level of the disease
- Serum amyloid A as a biomarker for endometrial endometrioid carcinoma to monitor disease recurrence and target response to therapy
- Signatera for carcinoid lung cancer
- Signatera molecular residual disease (MRD) assay for:
 - i. Alveolar soft tissue sarcoma
 - ii. Breast cancer
 - iii. Colorectal cancer
 - iv. Cutaneous melanoma
 - v. Gastric adenocarcinoma
 - vi. Ovarian sex cord stromal tumor
 - vii. Pancreatic cancer
 - viii. Prostate cancer
 - ix. Renal cell carcinoma
 - x. Uterine cancer
- Solid Tumor Expanded Panel (Quest)
- Strata Select
- TargetPrint gene expression test for evaluation of estrogen receptor, progesterone receptor, and HER2receptor status in breast cancer
- Tempus Tumor Origin (TO) testing
- The 41-gene signature assay
- Theros CancerType ID (bioTheranostics Inc., San Diego, CA)
- Thymidylate synthase
- Thyroid GuidePx
- TMPRSS fusion genes for prostate cancer
- Topographic genotyping (Pancragen (formerly PathFinderTG))
- Total (whole) gene sequencing for cancer
- TP53 mutation analysis for ovarian cancer
- UriFind Blood Cancer Assay for bladder cancer
- UroAmp MRD for bladder cancer
- UroCor cytology panels (DD23 and P53) for bladder cancer
- Vascular Endothelial Growth Factor (VEGF) except for Castleman's disease
- Vascular endothelial growth factor receptor 2 (VEGFR2) expression for identifying persons with colorectal cancer that is likely to respond to VEGF inhibition, and other indications
- Whole exome sequencing (somatic mutations) (e.g., EXaCT-1 Whole Exome Testing) for cancer.

Any of the following circulating tumor markers are also considered experimental, investigational, or unproven for screening asymptomatic subjects for cancer, diagnosis, staging, routine surveillance of cancer and monitoring the response to treatment:

a2-PAG	CA-SCC	MAM-6	TAG12
AMACR	Cathepsin-D, Cathepsin-L	Motility-related protein (MRP)	TAG72
	Cyclin E (fragments or whole length)	Multidrug resistance glycoprotein (Mdr1)	TAG72.3
BCM	DU-PAN-2		TAG72.5
CA195	Early prostate cancer antigen (EPCA)	NSE	TATI
CA242	Guanylyl cyclase C (Previstage GCC molecular test)		Thrombospondin-1 (THBS-1)
CA50	Hepsin	PCA3 (DD3) / UpM3	Thymosin B15
CA549	Human kallikrein 2 (HK2)	PNA/ELLA	TNF-a
CA72-4	LASA	Prostate stem cell antigen (PSCA)	Topoisomerase II Alpha (TOP2A)
CAM17-1	LPA	SCC	TPA
CAM26	M 26	SLEX	Thymosin B15
CAM29	M 29	SPAN-1	Nuclear Matrix Protein 66 (NMP66)
CAR-3	MSA	SLX	Anti-malignin antibody screen (AMAS) test
CYFRA21-1	MCA	ST-439	

References:

1. Aaberg TM Jr, Cook RW, Oelschlager K, et al. Current clinical practice: Differential management of uveal melanoma in the era of molecular tumor analyses. *Clin Ophthalmol*. 2014;8:2449-2460.
2. Abbosh PH, Plimack ER. Measuring the efficacy and value of urothelial cancer urinary biomarkers. *Ann Intern Med*. 2015;163(12):954-955.
3. Abeloff MD, Armitage JO, Niederhuber JE, et al. *Clinical Oncology*. 3rd ed. Philadelphia, PA. Churchill Livingstone; 2004: 2369.
4. Abida W, Patnaik A, Campbell D, et al.; TRITON2 investigators. Rucaparib in men with metastatic castration-resistant prostate cancer harboring a BRCA1 or BRCA2 gene alteration. *J Clin Oncol*. 2020;38(32):3763-3772.
5. American Cancer Society (ACS). Ovarian cancer has early symptoms. First national consensus on common warning signs. ACS News Center. Atlanta, GA: ACS; June 14, 2007.
6. American College of Obstetricians and Gynecologists (ACOG). Evaluation and management of adnexal masses. ACOG Practice Bulletin No. 174. Washington, DC: ACOG; November 2016.
7. American College of Obstetricians and Gynecologists (ACOG). Position of the American College of Obstetricians and Gynecologists Committee on Gynecologic Practice Regarding OvaCheck. Washington, DC: ACOG; February 25, 2004.
8. American College of Obstetricians and Gynecologists (ACOG). The role of the generalist obstetrician-gynecologist in the early detection of ovarian cancer. ACOG Committee Opinion No. 280. Washington, DC: ACOG; December 2002.
9. American College of Physicians. Screening for ovarian cancer: Recommendations and rationale. *Ann Intern Med*. 1994 J;121(2):141-142.
10. American Medical Association (AMA). CPT proprietary laboratory analyses (PLA) codes: long descriptor. April 6, 2022. Available at: <https://www.ama-assn.org/system/files/cpt-pla-codes-long.pdf>. Accessed December 11, 2024
11. American Society of Clinical Oncology. 1997 update of recommendations for the use of tumor markers in breast and colorectal cancer. Adopted on November 7, 1997 by the American Society of Clinical Oncology. *J Clin Oncol*. 1998;16(2):793-795.
12. American Society of Clinical Oncology. Clinical practice guidelines for the use of tumor markers in breast and colorectal cancer. Adopted on May 17, 1996 by the American Society of Clinical Oncology. *J Clin Oncol*. 1996;14(10):2843-2877.

13. American Thyroid Association (ATA) Guidelines Taskforce on Thyroid Nodules and Differentiated Thyroid Cancer, Cooper DS, Doherty GM, Haugen BR, et al. Revised American Thyroid Association management guidelines for patients with thyroid nodules and differentiated thyroid cancer. *Thyroid*. 2009;19(11):1167-1214.
14. Anceschi U, Tuderti G, Lugnani F, et al. Novel diagnostic biomarkers of prostate cancer: An update. *Curr Med Chem*. 2019;26(6):1045-1058.
15. Bareche Y, Venet D, Ignatiadis M, et al. Unravelling triple-negative breast cancer molecular heterogeneity using an integrative multiomic analysis. *Ann Oncol*. 2018;29(4):895-902.
16. Baron TH, Mallery JS, Hirota WK, et al. The role of endoscopy in the evaluation and treatment of patients with pancreaticobiliary malignancy. *Gastrointest Endosc*. 2003;58(5):643-649.
17. Blue Cross Blue Shield Association (BCBSA), Technology Evaluation Center (TEC). Use of genesearch breast lymph node assay to detect sentinel node metastases in early stage breast cancer. TEC Assessment Program. Chicago, IL:BCBSA; 2007; 22(8).
18. Blue Cross Blue Shield Association (BCBSA), Technology Evaluation Center (TEC). KRAS mutations and epidermal growth factor receptor inhibitor therapy in metastatic colorectal cancer. TEC Assessment Program. Chicago, IL: BCBSA; January 2009;25(6).
19. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Special Report: Pharmacogenomics of cancer-candidate genes. TEC Assessment Program. Chicago, IL: BCBSA; November 2007;22(5).
20. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Special report: Recent developments in prostate cancer genetics and genetic testing. TEC Assessments in Press. Chicago, IL: BCBSA; September 2008.
21. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Gene expression profiling for women with lymph-node-positive breast cancer to select adjuvant chemotherapy treatment. TEC Assessment Program. Chicago, IL: BCBSA; November 2010;25(1).
22. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Special report: Multiple molecular testing of cancers to identify targeted therapies. TEC Assessments in Press. Chicago, IL: BCBSA; February 2013.
23. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Actions Taken by the BlueCross BlueShield Association Medical Advisory Panel (MAP). Chicago, IL: BCBSA; February 19, 2014.
24. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Gene expression analysis for prostate cancer management. TEC Assessment Program. Chicago, IL: BCBSA; April 2014;28(11).

25. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Mutianalyte testing for evaluation of adnexal masses. TEC Assessment Program. Chicago, IL: BCBSA; April 2013;27(8).
26. BlueCross BlueShield Association (BCBSA). Gene expression analysis for prostate cancer management. TEC Assessment. Chicago, IL: BCBSA; January 2015; 29(9).
27. BlueCross BlueShield Association (BCBSA). Gene expression profiling in women with lymph node-negative breast cancer to select adjuvant chemotherapy. TEC Assessment. Chicago, IL: BCBSA; October 2014;29(3).
28. BlueCross BlueShield Association (BCBSA). Technology Evaluation Center (TEC). Multi-analyte testing for the evaluation of adnexal masses. TEC Assessment Program. Chicago, IL: BCBSA; 2013.
29. Centers for Medicare & Medicare Services (CMS). Local Coverage Determination (LCD): MolDX: Breast Cancer IndexSM Genetic Assay (L35294). Palmetto GBA – MAC Part B. Medicare Coverage Database. Baltimore, MD: CMS; effective November 3, 2014.
30. Mottok A, Wright G, Rosenwald A, et al. Molecular classification of primary mediastinal large B-cell lymphoma using routinely available tissue specimens. *Blood*. 2018;132(22):2401-2405.
31. National Cancer Institute at the National Institutes of Health (NCI). NCI dictionary of cancer terms. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/serum-tumor-marker-test>. Accessed December 11, 2024
32. National Cancer Institute (NCI). Ovarian Cancer (PDQ): Screening. Health Professional Version. Bethesda, MD: NCI; updated February 20, 2004.
33. National Cancer Institute (NCI). Questions and answers: OvaCheck TM and NCI/FDA Ovarian Cancer Clinical Trials using proteomics technology. NCI News. Bethesda, MD: NCI; March 22, 2004. Available at: <http://www.cancer.gov/newscenter/pressreleases/ProteomicsOvarian>. Accessed December 11, 2024
34. National Cancer Institute. Carcinoma of unknown primary treatment (PDQ®). Bethesda, MD: NCI; 2008.
35. National Cancer Institute. Hormone therapy with or without combination chemotherapy in treating women who have undergone surgery for node-negative breast cancer (the TAILORx Trial). ClinicalTrials.gov ID. NCT00310180. Bethesda, MD: National Library of Medicine; updated August 11, 2009.
36. National Collaborating Centre for Cancer. Diagnosis and management of metastatic malignant disease of unknown primary origin. Developed for NICE. Cardiff, UK: National Collaborating Centre for Cancer; July 2010.
37. National Comprehensive Cancer Network (NCCN). Acute myeloid leukemia. NCCN Clinical Practice Guidelines in Oncology v.1.2009. Fort Washington, PA: NCCN; September 2008.
38. National Comprehensive Cancer Network (NCCN). Acute myeloid leukemia. NCCN Clinical Practice Guidelines in Oncology v.3.2020. Fort Washington, PA: NCCN 2020

39. National Comprehensive Cancer Network (NCCN). B-cell lymphomas. NCCN Clinical Practice Guidelines in Oncology, version 1.2019. Fort Washington, PA: NCCN; 2018.
40. National Comprehensive Cancer Network (NCCN). Biomarkers Compendium. NCCN: Fort Washington, PA: NCCN; 2019.
41. National Comprehensive Cancer Network (NCCN). Bladder cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2014. Fort Washington, PA: NCCN; 2014.
42. National Comprehensive Cancer Network (NCCN). Bladder cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2019. Fort Washington, PA: NCCN; 2019.
43. National Comprehensive Cancer Network (NCCN). Bladder cancer. NCCN Clinical Practice Guidelines in Oncology, Version 6.2020. Fort Washington, PA: NCCN; 2020.
44. National Comprehensive Cancer Network (NCCN). Bladder cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2024. Plymouth Meeting, PA: NCCN; April 16, 2024.
45. National Comprehensive Cancer Network (NCCN). Bone cancer. Clinical Practice Guideline in Oncology, Version 1.2020. Fort Washington, PA: NCCN: 2020.
46. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2024. Plymouth Meeting, PA: NCCN; January 25, 2024.
47. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2011. Fort Washington, PA: NCCN; 2011.
48. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2013. Fort Washington, PA: NCCN; 2013.
49. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2015. Fort Washington, PA: NCCN; 2015.
50. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2020. Fort Washington, PA: NCCN; 2020.
51. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2021. Plymouth Meeting, PA: NCCN; 2021.
52. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2022. Plymouth Meeting, PA: NCCN; December 20, 2021.
53. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2024. Plymouth Meeting, PA: NCCN; March 11, 2024.
54. National Comprehensive Cancer Network (NCCN). Breast cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2018. Fort Washington, PA: NCCN; 2018.

55. National Comprehensive Cancer Network (NCCN). CA 19-9 expression. NCCN Biomarkers Compendium. Plymouth Meeting, PA:NCCN; 2021.
56. National Comprehensive Cancer Network (NCCN). Central nervous system cancers. NCCN Clinical Practice Guidelines in Oncology, version 2.2018. Fort Washington, PA: NCCN; 2018.
57. National Comprehensive Cancer Network (NCCN). Chronic lymphocytic leukemia/small lymphocytic lymphoma. NCCN Clinical Practice Guidelines in Oncology, version 2.2019. Fort Washington, PA: NCCN, 2018.
58. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2015. Fort Washington, PA: NCCN; 2015.
59. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2018. Fort Washington, PA: NCCN; 2018.
60. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2018. Fort Washington, PA: NCCN; 2018.
61. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2018. Fort Washington, PA: NCCN; 2018.
62. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2019. Fort Washington, PA: NCCN; 2019.
63. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2020. Fort Washington, PA: NCCN; 2020.
64. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2021. Plymouth Meeting, PA: NCCN; 2021.
65. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2022. Plymouth Meeting, PA: NCCN; 2022.
66. National Comprehensive Cancer Network (NCCN). Colon cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2022. Plymouth Meeting, PA: NCCN; 2022.
67. National Comprehensive Cancer Network (NCCN). Copy number alterations. NCCN Biomarkers Compendium. Plymouth Meeting, PA: NCCN; Accessed December 11, 2024
68. National Comprehensive Cancer Network (NCCN). Cutaneous melanoma. NCCN Clinical Practice Guidelines in Oncology, version 1.2019. Fort Washington, PA: NCCN; 2018.
69. National Comprehensive Cancer Network (NCCN). Cutaneous melanoma. NCCN Clinical Practice Guidelines in Oncology, Version 2.2019. Fort Washington, PA: NCCN; 2019.

70. National Comprehensive Cancer Network (NCCN). Cutaneous melanoma. NCCN Clinical Practice Guidelines in Oncology, Version 2.2019. Fort Washington, PA: NCCN; 2019.
71. National Comprehensive Cancer Network (NCCN). Cutaneous melanoma. NCCN Clinical Practice Guidelines in Oncology, Version 1.2020. Fort Washington, PA: NCCN; 2020.
72. National Comprehensive Cancer Network (NCCN). Cutaneous melanoma. NCCN Clinical Practice Guidelines in Oncology, Version 3.2020. Fort Washington, PA: NCCN; 2020.
73. National Comprehensive Cancer Network (NCCN). Esophageal and esophagogastric junction cancers. NCCN Clinical Practice Guidelines in Oncology v.2.2011. Fort Washington, PA: NCCN; May, 2011.
74. National Comprehensive Cancer Network (NCCN). Head and neck cancers. NCCN Clinical Practice Guidelines in Oncology, Version 2.2022. Plymouth Meeting, PA: NCCN, 2022.
75. National Comprehensive Cancer Network (NCCN). Head and neck cancers. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023. Plymouth Meeting, PA: NCCN, 2023.
76. National Comprehensive Cancer Network (NCCN). Head and neck cancers. NCCN Clinical Practice Guidelines in Oncology, Version 3.2024. Plymouth Meeting, PA: NCCN, 2024.
77. National Comprehensive Cancer Network (NCCN). Hepatobiliary cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2021. Plymouth Meeting, PA: NCCN; 2021.
78. National Comprehensive Cancer Network (NCCN). Hepatobiliary cancers. NCCN Clinical Practice Guidelines in Oncology v.1.2010. Fort Washington, PA: NCCN; 2010.
79. National Comprehensive Cancer Network (NCCN). Hepatobiliary cancers. NCCN Clinical Practice Guidelines in Oncology, Version 2.2015. Fort Washington, PA: NCCN; 2015.
80. National Comprehensive Cancer Network (NCCN). Invasive breast cancer. NCCN Biomarkers Compendium. Plymouth Meeting, PA; NCCN; February 2024.
81. National Comprehensive Cancer Network (NCCN). Kidney cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2022. Plymouth Meeting, PA: NCCN; 2022.
82. National Comprehensive Cancer Network (NCCN). Lung cancer screening. NCCN Clinical Practice Guidelines in Oncology, Version 2.2024. Plymouth Meeting, PA: NCCN; October 18, 2023.
83. National Comprehensive Cancer Network (NCCN). Mekinist. NCCN Drugs & Biologics Compendium. Fort Washington, PA: NCCN; 2018.
84. National Comprehensive Cancer Network (NCCN). Melanoma. NCCN Clinical Practice Guidelines in Oncology, Version 2.2018. Fort Washington, PA: NCCN; 2018.
85. National Comprehensive Cancer Network (NCCN). Melanoma. NCCN Drugs & Biologics Compendium. Fort Washington, PA: NCCN; 2018.

86. National Comprehensive Cancer Network (NCCN). Melanoma: Cutaneous. NCCN Clinical Practice Guidelines in Oncology, Version 1.2024. Plymouth Meeting, PA:NCCN; April 3, 2024.
87. National Comprehensive Cancer Network (NCCN). Melanoma: Cutaneous. NCCN Clinical Practice Guidelines in Oncology, Version 2.2022. Plymouth Meeting, PA: NCCN; 2021.
88. National Comprehensive Cancer Network (NCCN). Microsatellite instability. NCCN Biomarkers Compendium. Plymouth Meeting, PA: NCCN; Accessed December 11, 2024
89. National Comprehensive Cancer Network (NCCN). Multiple myeloma. NCCN Clinical Practice Guidelines in Oncology, Version 2.2013. Fort Washington: PA: NCCN; 2013.
90. National Comprehensive Cancer Network (NCCN). Myelodysplastic syndromes. NCCN Clinical Practice Guidelines in Oncology, version 1.2020. Fort Washington, PA: NCCN; 2020.
91. National Comprehensive Cancer Network (NCCN). Myelodysplastic syndromes. NCCN Clinical Practice Guidelines in Oncology, version 2.2020. Fort Washington, PA: NCCN; 2020.
92. National Comprehensive Cancer Network (NCCN). Myeloproliferative neoplasms. NCCN Clinical Practice Guidelines in Oncology, version 2.2019. Fort Washington, PA: NCCN; 2019.
93. National Comprehensive Cancer Network (NCCN). Myeloproliferative neoplasms. NCCN Clinical Practice Guidelines in Oncology, version 3.2019. Fort Washington, PA: NCCN; 2019.
94. National Comprehensive Cancer Network (NCCN). Non-small cell lung cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2019; Fort Washington, PA: NCCN; 2019.
95. National Comprehensive Cancer Network (NCCN). Non-small cell lung cancer. NCCN Clinical Practice Guidelines in Oncology, Version 5.2019. Fort Washington, PA: NCCN; 2019.
96. National Comprehensive Cancer Network (NCCN). Non-small cell lung cancer. NCCN Clinical Practice Guidelines in Oncology, Version 6.2020. Fort Washington, PA: NCCN; 2020.
97. National Comprehensive Cancer Network (NCCN). Non-small cell lung cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023. Plymouth Meeting, PA: NCCN; December 22, 2022.
98. National Comprehensive Cancer Network (NCCN). Non-small cell lung cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2024. Plymouth Meeting, PA: NCCN; February 9, 2024.
99. National Comprehensive Cancer Network (NCCN). Occult primary (cancer of unknown primary [CUP]). NCCN Clinical Practice Guidelines in Oncology v.1.2010. Fort Washington, PA: NCCN; 2010.
100. National Comprehensive Cancer Network (NCCN). Occult primary. NCCN Clinical Practice Guidelines in Oncology v.1.2009. Fort Washington, PA: NCCN; July 2008.
101. National Comprehensive Cancer Network (NCCN). Ovarian cancer. NCCN Clinical Practice Guidelines in Oncology, version 2.2015. Fort Washington, PA: NCCN; 2015.

102. National Comprehensive Cancer Network (NCCN). Ovarian cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2018. Fort Washington, PA: NCCN; 2018.
103. National Comprehensive Cancer Network (NCCN). Ovarian cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2014. Fort Washington, PA: NCCN; 2014.
104. National Comprehensive Cancer Network (NCCN). Ovarian cancer/fallopian tube cancer/primary peritoneal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023. Plymouth Meeting, PA: NCCN; 2023.
105. National Comprehensive Cancer Network (NCCN). Ovarian cancer/fallopian tube cancer/primary peritoneal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2024. Plymouth Meeting, PA: NCCN; 2023.
106. National Comprehensive Cancer Network (NCCN). Ovarian cancer including fallopian tube cancer and primary peritoneal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2024. Plymouth Meeting, PA: NCCN; January 17, 2024.
107. National Comprehensive Cancer Network (NCCN). Pancreatic adenocarcinoma. NCCN Clinical Practice Guidelines in Oncology, Version 1.2022. Plymouth Meeting, PA: NCCN; 2022.
108. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Biomarkers Compendium. Fort Washington, PA: NCCN; 2019.
109. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2015. Fort Washington, PA: NCCN; 2015.
110. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023. Plymouth Meeting, PA: NCCN; 2022.
111. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2017. Fort Washington, PA: NCCN; 2017.
112. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2018. Fort Washington, PA: NCCN; 2018.
113. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2020. Fort Washington, PA: NCCN; 2020.
114. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2022. Plymouth Meeting, PA: NCCN; 2022.
115. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2018. Fort Washington, PA: NCCN; 2018.
116. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2019. Fort Washington, PA: NCCN; 2019.

117. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2024. Plymouth Meeting, PA: NCCN; 2024.
118. National Comprehensive Cancer Network (NCCN). Prostate cancer early detection. NCCN Clinical Practice Guidelines in Oncology, Version 2.2019. Plymouth Meeting, PA: NCCN; 2019.
119. National Comprehensive Cancer Network (NCCN). Prostate cancer early detection. NCCN Clinical Practice Guidelines in Oncology, Version 1.2022. Plymouth Meeting, PA: NCCN; 2022.
120. National Comprehensive Cancer Network (NCCN). Prostate cancer early detection. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023. Plymouth Meeting, PA: NCCN; 2023.
121. National Comprehensive Cancer Network (NCCN). Prostate cancer early detection. NCCN Clinical Practice Guidelines in Oncology, Version 2.2024. Plymouth Meeting, PA: NCCN; 2024.
122. National Comprehensive Cancer Network (NCCN). Rectal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2018. Fort Washington, PA: NCCN; 2018.
123. National Comprehensive Cancer Network (NCCN). Rectal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 2.2019. Fort Washington, PA: NCCN; 2019.
124. National Comprehensive Cancer Network (NCCN). Rectal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2020. Fort Washington, PA: NCCN; 2020.
125. National Comprehensive Cancer Network (NCCN). Rectal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 6.2020. Fort Washington, PA: NCCN; 2020.
126. National Comprehensive Cancer Network (NCCN). Rectal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2022. Plymouth Meeting, PA: NCCN; 2022.
127. National Comprehensive Cancer Network (NCCN). Rectal cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2022. Plymouth Meeting, PA: NCCN; 2022.
128. National Comprehensive Cancer Network (NCCN). Small cell lung cancer. NCCN Clinical Practice Guideline in Oncology, Version 2.2017. Fort Washington, PA: NCCN; 2017.
129. National Comprehensive Cancer Network (NCCN). Small cell lung cancer. NCCN Clinical Practice Guidelines in Oncology, Version 1.2019. Fort Washington, PA: NCCN; 2019.
130. National Comprehensive Cancer Network (NCCN). Soft tissue sarcoma. NCCN Clinical Practice Guidelines in Oncology, Version 1.2022. Plymouth Meeting, PA: NCCN; 2022.
131. National Comprehensive Cancer Network (NCCN). Systemic mastocytosis. NCCN Clinical Practice Guidelines in Oncology, Version 1.2020. Plymouth Meeting, PA: NCCN; 2020.
132. National Comprehensive Cancer Network (NCCN). Thyroid carcinoma. NCCN Clinical Practice Guidelines in Oncology, version 3.2018. Fort Washington, PA: NCCN; 2018.

133. National Comprehensive Cancer Network (NCCN). Tumor mutational burden. NCCN Biomarkers Compendium. Plymouth Meeting, PA: NCCN; Accessed December 11, 2024
134. National Comprehensive Cancer Network (NCCN). Uterine neoplasms. NCCN Clinical Practice Guidelines in Oncology, Version 2.2015. Fort Washington, PA: NCCN; 2015.
135. National Comprehensive Cancer Network. Clinical practice guideline: Uterine neoplasms. Version 1.2022. NCCN: Plymouth Meeting, PA.
136. National Comprehensive Cancer Network (NCCN). Gastric cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2016. Fort Washington, PA: NCCN; 2016.
137. National Comprehensive Cancer Network. Clinical practice guideline: Gastric cancer. Version 2.2022. NCCN: Plymouth Meeting, PA.
138. National Comprehensive Cancer Network (NCCN). Head and neck cancers. NCCN Clinical Practice Guidelines in Oncology, version 2.2018. Fort Washington, PA:NCCN, 2018.
139. National Comprehensive Cancer Network (NCCN). HPV infection. NCCN Biomarkers Compendium. Fort Washington, PA: NCCN. 2018.
140. National Comprehensive Cancer Network (NCCN). HPV. NCCN Biomarkers Compendium. Fort Washington, PA: NCCN, 2018.
141. National Comprehensive Cancer Network (NCCN). Melanoma. NCCN Clinical Practice Guidelines in Oncology, Version 2.2016. Fort Washington, PA: NCCN; 2016.
142. National Comprehensive Cancer Network (NCCN). Non-small cell lung cancer. NCCN Clinical Practice Guidelines in Oncology, Version 4.2017. Fort Washington, PA: NCCN; 2017.
143. National Comprehensive Cancer Network (NCCN). Pancreatic adenocarcinoma. NCCN Clinical Practice Guidelines in Oncology, Version 2.2016. Fort Washington, PA: NCCN; 2016.
144. National Comprehensive Cancer Network (NCCN). Pancreatic adenocarcinoma. NCCN Clinical Practice Guidelines in Oncology, version 1.2019. Fort Washington, PA: NCCN; 2018.
145. National Comprehensive Cancer Network (NCCN). Prostate cancer. NCCN Clinical Practice Guidelines in Oncology, Version 3.2016. Fort Washington, PA: NCCN; 2016.
146. National Horizon Scanning Center (NHSC). Prostate cancer gene 3 (ProgenSA PCA3) assay in the diagnosis of prostate cancer. Horizon Scanning Technology Briefing. Birmingham, UK: NHSC; December 2006.
147. National Horizon Scanning Centre (NHSC). NMP22 BladderChek proteomic assay for the detection of bladder cancer - horizon scanning technology note. Birmingham, UK: NHSC; 2006.

148. National Horizon Scanning Centre (NHSC). Update: OVA1™ test for the assessment of suspected ovarian cancer. Horizon Scanning Report. Birmingham, UK: National Horizon Scanning Centre, University of Birmingham; 2012.
149. National Horizon Scanning Centre (NHSC). UPDATED: RealTime mS9 Colorectal Cancer (CRC) Assay for the early detection of colorectal cancer. Horizon Scanning Review. Birmingham, UK: National Horizon Scanning Centre (NHSC); 2012.
150. National Institute for Health and Care Excellence (NICE). Prolaris gene expression assay for assessing long-term risk of prostate cancer progression. MedTech Innovation Briefing [MIB65]. London, UK: NICE; May 2016.
151. National Institute for Health and Care Excellence (NICE). Caris Molecular Intelligence for guiding cancer treatment. Medtech Innovation Briefing [MIB120]. London, UK: NICE; September 2017.
152. National Institute for Health and Care Excellence (NICE). Diagnosing prostate cancer: PROGENSA PCA3 assay and Prostate Health Index. Diagnostics Guidance (DG) No. 17. London, UK: National Institute for Health and Care Excellence (NICE); June 2, 2015.
153. National Institute for Health and Care Excellence (NICE). EndoPredict gene expression profiling assay for assessing risk of breast cancer recurrence. Medtech Innovation Briefing 44. London, UK: NICE; November 2015.
154. National Institute for Health and Care Excellence (NICE). The Prosigna gene expression profiling assay for assessing long-term risk of breast cancer recurrence. Medtech Innovation Briefing 27. London, UK: NICE; March 2015.
155. National Institute for Health and Care Excellence (NICE). Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat. Diagnostics Guidance (DG) 10. London, UK: NICE; September 2013.
156. National Institute for Health and Care Excellence (NICE). Signatera for detecting molecular residual disease from solid tumour cancers. Medtech Innovation Briefing (MIB) 307. London, UK: NICE: October 4, 2022.
157. National Institute for Health and Clinical Excellence (NICE). Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer. Technology Appraisal Guidance 118. London, UK: NICE; January 2007.
158. National Institute for Health and Clinical Excellence (NICE). Diagnosis and management of metastatic malignant disease of unknown primary origin. Clinical Guideline. Draft for Consultation. London, UK: NICE; December 2009.
159. National Institutes of Health (NIH), Early Detection Research Network (EDRN). MiPS (Mi Prostate Score Urine Test. Biomarkers. Bethesda, MD: NIH; 2019. Available at: <https://edrn.nci.nih.gov/biomarkers/mips-mi-prostate-score-urine-test>. Accessed December 11, 2024

160. Society of Gynecologic Oncologists (SGO). Society of Gynecologic Oncologists statement regarding OvaCheck™. Position Statements. Chicago, IL: SGO; February 7, 2004. Available at: http://www.sgo.org/policy/position_statement.cfm. Accessed December 11, 2024
161. Society of Gynecologic Oncologists (SGO).. Statement regarding OvaSure. Chicago, IL: SGO; July 2, 2008. Available at: <http://blog.targethealth.com/?p=1492>. Accessed December 11, 2024