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MEDICAL POLICY – 6.01.31

Mammography-based AI (Image-only) Risk Prediction Models for Breast Cancer

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Select a hyperlink below to be directed to that section.

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Artificial intelligence (AI) is a type of computer technology that can analyze large amounts of information and identify patterns. New AI-based software has been developed to review breast imaging studies and estimate a person's chance of developing breast cancer in the future. Breast cancer occurs when cells in the breast grow out of control. Screening mammography is an X-ray of the breasts that is used to look for signs of breast cancer before symptoms develop. Some AI tools are designed to estimate a person's 5-year risk of developing breast cancer based on images from bilateral screening mammography. This information is intended to be used to help guide discussions about breast cancer screening and prevention. Mammography-based AI risk prediction software used to estimate a person's 5-year risk of developing breast cancer is considered investigational (unproven). There is not enough evidence to show it is effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
Mammography-based AI risk prediction software for bilateral screening mammography	**Use of mammography-based AI (artificial intelligence) risk prediction software for individuals undergoing bilateral screening mammography to estimate their 5-year risk of developing breast cancer is considered investigational.**

Coding

Code	Description
CPT	
19499	Unlisted procedure, breast

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Using more than one mammography-based AI risk prediction model is not indicated to estimate the five-year breast cancer risk. Paired use of a clinical risk prediction model alongside a mammography-based AI risk prediction model may be appropriate in subgroups where AI performance is less well established. This limitation does not apply to clinical or comprehensive family-history-based risk-assessment models, or to genetic testing performed to assess hereditary breast cancer risk. Periodic re-assessment of risk is only recommended when risk factors change.

Increased Risk Management Pathway

For individuals greater than or equal to 35 years of age with a five-year risk of invasive breast cancer greater than or equal to 1.7% as calculated per the Gail Model or imaging-based risk assessment models (e.g., Clairity and Mirai), the following screening and follow-up are

recommended by the **National Comprehensive Cancer Network Breast Cancer Screening and Diagnosis v1.2026**:

- Clinical encounter every 6 to 12 months;
    - To begin when identified as being at increased risk
    - At minimum, the clinical encounter should include medical and family history review and encompass ongoing risk assessment (by age 25 years), risk reduction counseling, and preferably a clinical breast examination, even in individuals who are asymptomatic when feasible. Known breast density should be factored into risk assessment if available from prior mammogram.

- Annual screening mammogram with tomosynthesis;
    - To begin when identified as being at increased risk

- Consider risk reduction strategies (See **NCCN guidelines Breast Cancer Risk Reduction v1.2026**).
    - Counsel individuals on healthy lifestyles and risk reduction options;
    - Risk-reducing agent(s);
    - Risk-reducing mastectomy

- Breast awareness;

- Consider annual breast magnetic resonance imaging (MRI) with and without contrast
    - Consider contrast-enhanced mammography (CEM) or molecular breast imaging (MBI) for those who qualify for but cannot undergo MRI. Whole breast ultrasound may be done if CEM or MBI is not available

Note: Individuals should undergo breast cancer risk assessment by age of 25 years and be counseled regarding the potential benefits, risk, and limitations of breast screening in the context of their risk stratification. Consider severe comorbid conditions limiting life expectancy (e.g., less than or equal to 10 years) and whether therapeutic interventions would be appropriate and acceptable to the individual.

Clairity Allix5

Performance Considerations in Specific Populations

Pivotal validation data for Clairity Allix5 demonstrated that the lower 95% confidence interval bound for time-dependent area under the curve (AUC[5]) fell below the pre-specified

discrimination performance goal of 0.64 in several subgroups when cancers diagnosed within 90 days of a positive index examination were excluded, including:

- Black;
- Hispanic;
- Asian;
- Age greater than or equal to 65 years;
- Age less than 50 years;
- Dense breasts; and
- Breast implants.

Imaging Acquisition Requirements

Mammography-based AI risk prediction software has been validated only on the imaging acquisition platforms and formats specified in the device's regulatory authorization or published validation studies. Clairity Allix5 has been validated on directly acquired bilateral 2D screening mammograms acquired from Hologic Selenia Dimensions or Lorad Selenia mammography systems. Synthetic 2D images, digital breast tomosynthesis–derived 2D images, and images acquired from other manufacturers' equipment are not within the validated acquisition profile and should not be used as input for clinical risk prediction with Allix5.

Evidence Review

Description

This evidence review addresses the use of mammography-based AI (artificial intelligence) risk prediction software intended to generate a five-year risk prediction of breast cancer based on a bilateral screening mammogram in eligible individuals without known breast cancer at presentation. The purpose of mammography-based AI risk prediction software in individuals undergoing bilateral screening mammography is to predict the five-year risk of individuals who will receive a diagnosis of breast cancer or develop breast cancer within the five-year timeframe.

The objective of this evidence review is to determine whether using mammography-based AI risk prediction software for breast cancer improves the net health outcome in individuals undergoing bilateral screening mammography.

Background

Breast Cancer Risk

Breast cancer is the most commonly diagnosed non-skin cancer in US women and remains a leading cause of cancer death. The American Cancer Society (ACS) estimates the average lifetime risk for a US female is approximately 13.1 percent (about 1 in 8) with a lifetime probability of breast-cancer death of approximately 2.3 percent (about 1 in 43).[1] For 2024 the ACS projected approximately 310,720 new invasive female breast cancers, 56,500 cases of female ductal carcinoma in situ, and 42,250 female breast-cancer deaths in the United States, plus 2,790 invasive cases and 530 deaths in men. Screening confers the greatest absolute benefit in individuals most likely to develop breast cancer, since the number of deaths averted per woman screened scales with baseline risk. Mammography in average-risk women has demonstrated a reduction in breast cancer mortality of approximately 20 percent, with smaller absolute benefit in younger women whose cancer incidence is lower.[2,3] Across the most recent decade of available data (2012–2021), invasive breast cancer incidence increased by approximately 1 percent per year, with a steeper trend in women younger than 50 (1.4 percent per year) than in women 50 or older (0.7 percent per year). As the incidence in younger populations continues to grow, conventional mammography will offer limited value for individual-level risk estimation in this group, as mammographic sensitivity is lower in younger women whose, typically, denser breast tissue obscures 2D imaging. Furthermore, established risk prediction models, calibrated principally on older cohorts and weighted toward lifetime-risk horizons, provide little discriminating signal at younger ages. Mammography for breast cancer is a controversial topic. Experts disagree on when to begin screening, when to end screening, and how often to screen. Compared with standard screening schedules, risk-based or personalized breast cancer screening has the potential to reduce false-positive recalls while detecting clinically significant cancers earlier.

Risk Prediction Models

Several breast-cancer risk prediction models are in routine clinical use, each developed to support a different decision point in the screening and prevention pathway. The Gail model Breast Cancer Risk Assessment Tool (BCRAT) and the Breast Cancer Screening Calculator (BCSC) calculator are typically used at routine screening encounters to identify women whose five- or ten-year risk crosses established thresholds for management decisions (i.e., chemoprevention discussion or supplemental imaging). Tyrer-Cuzick International Breast Intervention Study (IBIS)

and the comprehensive-pedigree models (BRCAPRO, Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm [BOADICEA]/Cancer Risk) are typically used in genetic-counseling and high-risk-clinic settings, where they support both estimation of residual lifetime risk and probability of carrying pathogenic variants in BRCA1/BRCA2 and related susceptibility genes. Collectively, these models share three important strengths. They draw on factors with established epidemiologic associations to breast cancer, they are inexpensive, non-invasive, and deployable from data routinely collected at clinical encounters, and they have been validated in large cohorts and incorporated into guideline-endorsed care pathways for decades. As **Table 1** details, however, they also share three important limitations. First, individual-level discrimination is modest across all five models: reported area under the receiver operating characteristic curve (AUROC) values cluster between approximately 0.58 and 0.65, leaving substantial overlap between women who do and do not subsequently develop breast cancer at any given risk score. Second, all five models were developed predominantly in cohorts of European ancestry, and external validations have demonstrated calibration drift in non-European populations and in younger women. Third, the output horizons of the five models are heterogeneous: only the Gail model and BCSC produce five-year invasive breast-cancer risk estimates on the scale used by the NCCN greater than or equal to 1.7% increased risk pathway, and of those two, only BCSC incorporates mammographic image information (breast density). The remaining three models output ten-year, lifetime, or mutation-probability estimates that would not directly support the greater than or equal to 1.7% five-year threshold without re-derivation.

The five-year greater than or equal to 1.7% threshold itself is well established in breast-cancer risk management. It corresponds to the entry criterion for the National Surgical Adjuvant Breast and Bowel Project initiated Breast Cancer Prevention Trial Part 1 (NSABP P-1) tamoxifen prevention trial, which demonstrated a 49% short-term reduction in invasive breast cancer incidence in eligible participants randomized to tamoxifen, and it remains the canonical threshold above which clinicians initiate the standard Increased Risk management cascade.[4,5] For individuals who meet this threshold and are greater than or equal to 35 years of age, the cascade includes clinical encounter every 6 to 12 months, annual digital mammography with tomosynthesis, consideration of annual breast MRI (with contrast-enhanced mammography, molecular breast imaging, or whole-breast ultrasound as alternatives where MRI is contraindicated or unavailable), counseling on risk-reduction strategies, and periodic risk reassessment. Risk-reduction agents, such as tamoxifen, raloxifene, anastrozole, and exemestane are routinely offered for this threshold, with tamoxifen as the only agent indicated for premenopausal individuals. In current practice, this means a 5-year breast-cancer risk estimate greater than or equal to 1.7%, produced by a tool whose output is calibrated to that horizon

(i.e., Gail and BCSC), an individual is routed into the Increased Risk management cascade described above.

Table 1. Breast Cancer Risk Prediction Models

Model	Description	Factors Included	Benefits	Limitations
The Breast Cancer Surveillance Consortium (BCSC) Risk Calculator[6]	Interactive tool designed to estimate 5-year risk of developing invasive breast cancer in those AFAB, including benign breast disease diagnoses and to estimate both 5-year and 10-year breast cancer risk. May have limited applicability for extensive family history beyond first-degree relatives.	5- and 10-year breast cancer risk calculations are based on 5 factors: • age • race/ethnicity • Family history of breast cancer in a first-degree relative (parent, sibling, or child) • History of breast biopsy (core biopsy, excisional biopsy, or fine-needle aspiration [FNA] with benign breast disease diagnosis if known) • BI-RADS breast density (radiologic assessment of the density of the breast tissue by a radiologist who interprets mammograms)	Accessible online	The calculator is NOT applicable to individuals who meet any of the following criteria: • Does not take into account beyond first-degree relatives • <35 years or >74 years of age • Previous diagnosis of the following: o Breast cancer o Ductal carcinoma in situ (DCIS) o Breast augmentation o Mastectomy
Gail Model[7]	Individualized breast cancer risk assessment computed based on SEER-specific breast cancer risk data with inclusion of personalized risk factors. Provides both 5-year and lifetime risk assessment. 5-year risk assessment	• Age • Age at menarche • Age at first live birth • Family history of breast cancer in first-degree relatives assigned female at birth (AFAB) • Number of previous breast biopsies	• Validated across multiple studies and cohorts • Accessible online • Available to assess eligibility for a risk-reducing agent	• Performance varies across racial and ethnic subgroups; published recalibrations exist for African American and Asian/Pacific Islander US women, but performance in other groups remains less well characterized

	≥1.67% used to assess eligibility for a risk-reducing agent.	• Diagnosis of atypical hyperplasia (AH)	• Periodic updates based on changes in breast cancer incidence data • Accounts for competing risks of mortality other than breast cancer	• Cannot be used for individuals <35 years of age • Considers only a fraction of family history data: o Only includes first-degree relative AFAB (paternal family history excluded) o Does not include ages of diagnoses of relatives' breast cancer o Does not include family history of other cancer diagnosis outside breast cancer o Does not include mantle radiation • Underestimates risk for development of breast cancer in: o Those with germline variants in known breast cancer predisposition genes such as BRCA1/2 o Those with a strong family history of breast cancer o Those with a family history of ovarian cancer in the maternal or

				paternal family lineage o Non-white individuals o Those with AH
International Breast Cancer Intervention Study (IBIS/Tyrer-Cuzick) [8]	Computerized model based on initial data from the United Kingdom Thames Cancer Registry 2005-2009. Attribution of risk based on family history data. Provides personalized breast cancer risk assessment based on individual risk factors and family history information. Both lifetime breast cancer risk (to age 85 in version 7+) and 10-year risk estimations are available.	• Age • Reproduction history (i.e., age at menarche, age at first live birth, age at menopause) • BMI • Exogenous hormone exposure (menopause hormone therapy) • Family history • History of breast biopsies and results (including AH and lobular carcinoma in situ [LCIS]) • Breast density • Genetic test results (BRCA1/2 only)	• Can be used in individuals <35 years of age • Accessible online • Simultaneous computation of risk for BRCA1/2 pathogenic mutation • Comprehensive incorporation of family history and overall family structures including: o Affected first-, second-, and third-degree (first cousins) relatives o Ovarian cancer diagnosis o Breast cancer diagnosis in those assigned male at birth (AMAB) o Unaffected relatives • Periodic updates based on breast cancer incidence data	• Does not consider risk from mantle radiation • Overestimates risk for development of breast cancer in: o Hispanic individuals as this model was validated in primarily White individuals in the United Kingdom o AH o LCIS o Dense breast • Routine clinical use of (PRS) in risk assessment is not encouraged

			• Accounts for competing risks of mortality other than breast cancer (have to select option) • Incorporates risk estimates from single-nucleotide polymorphisms (SNPs) (polygenic risk score [PRS]), if available	
BRCAPro[9]	Bayesian carrier-probability model that uses Mendelian segregation analysis applied to a multi-generational family pedigree of breast and ovarian cancers. Penetrance and prevalence parameters for BRCA1/2 are derived from a systematic review of the published literature. Produces lifetime breast-cancer risk estimates derived from carrier-status modeling.	• Bayesian model assuming autosomal-dominant inheritance, based on family history incorporating unaffected relatives compared with SEER data • BRCA1/2 penetrance/prevalence data are based on a systematic review of the literature	• Predicts individual and combined probabilities for carrying germline BRCA1/2 pathogenic/likely pathogenic variants • Incorporates ethnicity and mastectomy	• Underestimates carrier frequency in families with ovarian cancer • Underestimates carrier frequency in families with prostate cancer • Performance characteristics in minority populations need further validation • Does not allow incorporation of third-degree relatives • Excludes limited or unknown information about family • Ages must be estimated, if they are unknown • Does not consider any genes besides BRCA1/2

				• Not freely available without registering
CanRisk Tool (BOADICEA v6)[10]	Comprehensive risk prediction tool that integrates multi-gene panel results, PRS, multi-generational family history of breast and non-breast cancers, lifestyle and hormonal factors, mammographic breast density, and tumor pathology where available. Prospectively validated for both carrier-probability prediction and prediction of subsequent cancer risk. Produces lifetime breast cancer and ovarian cancer risk estimates.	• Models the risks of breast and ovarian cancer based on family history and genotypes for germline variants in BRCA 1/2, PALB2, CHEK2, ATM, BARD1, RAD51C, and RAD51D • Incorporates the effects of common genetic variants (summarized as PRS), lifestyle, hormonal and clinical features, breast density, and disease pathology • Prospectively validated, both for the prediction of carrier probabilities and prediction of subsequent cancer risk	• Accessible online • Includes personal and lifestyle risk factors • Includes family history of breast/non-breast cancers in immediate/distant relatives • Provides risk estimates for breast and ovarian cancer • Inclusive of patients with personal history of breast cancer (tumor pathology) • Can be used with susceptibility germline variants of high/moderate risk other than BRCA1/2 • Incorporates risk estimates from SNPs (PRS), if available	• Routine use of PRS in risk assessment is not encouraged • Non-white population • Does not take into account personal risk factors such as breastfeeding, prior breast biopsy, and atypia • Does not include mantle radiation

Adapted from NCCN Guidelines v1.2026 Breast Cancer Risk Reduction. [11,]

AFAB: assigned female at birth; AH: atypical hyperplasia; AMAB: assigned male at birth; BI-RADS: breast imaging reporting and data system; BOADICEA: The breast and ovarian analysis of disease incidence and carrier estimation algorithm; DCIS: ductal carcinoma in situ; FNA: fine-needle aspiration; LCIS: lobular carcinoma in situ; PRS: polygenic risk score; SNP: single nucleotide polymorphism

[a] Version 3 of the BCSC Risk Calculator extends the model to include BMI, extended (beyond first-degree) family

history, and age at first live birth, with modestly improved discrimination.[1,2,] The v3 update is not yet reflected in current NCCN guidance.

Clairity Allix5 (Clairity Breast)

Clairity Allix5 is an image-based deep-learning software device that generates a five-year breast cancer risk prediction from a routine bilateral screening mammogram. The algorithm inputs the 4 standard 2D screening views (right craniocaudal [RCC], left craniocaudal [LCC], right mediolateral oblique [RMLO], left mediolateral oblique [LMLO]) acquired from Hologic Selenia Dimensions or Lorad Selenia mammography systems and analyzes pixel-level imaging features and characteristics that correlate with future breast cancer development. Synthetic 2D images and images from non-Hologic acquisition platforms are not supported. The mammography-based AI algorithm provides a prediction of the percentage probability that the individual will receive a diagnosis of breast cancer or develop breast cancer within the five-year timeframe following the screening mammogram.

Mirai

Mirai is a deep learning model that produces a personalized risk score that generates a five-year breast cancer risk prediction from a routine bilateral screening mammogram. The algorithm inputs the four standard 2D screening views (RCC, LCC, RMLO, LMLO) acquired from Hologic Selenia Dimensions or Lorad Selenia mammography systems and consists of four modules: an image encoder, an image aggregator, a risk factor predictor, and an additive-hazard layer. During the risk factor predictor module, an individual's traditional risk factors (such as, age, weight, and hormonal factors) or predicted traditional risk factors are incorporated into the algorithm to allow for mammograms as the sole input. The mammography-based AI algorithm provides a prediction of the percentage probability that the individual will receive a diagnosis of breast cancer or develop breast cancer within the 5-year timeframe following the screening mammogram.

Summary of Evidence

For individuals undergoing bilateral screening mammography who receive mammography-based AI risk prediction software, the evidence includes a pivotal validation study supporting De Novo authorization of Clairity Allix5, two systematic reviews, and several validation studies of the

Mirai algorithm. Relevant outcomes are overall survival, disease-specific survival, test validity, reclassification of risk, change in management, reduction in breast cancer incidence, and quality of life. The Allix5 pivotal data demonstrated a five-year area under the curve of 0.70 (95% CI, 0.69 to 0.72) in the total population and 0.66 (95% CI, 0.66 to 0.68) in the analysis excluding cancers diagnosed within 90 days of a positive index examination. No studies comparing Clairity Allix5 to clinical risk prediction models (e.g., Gail, Tyrer Cuzick, BCSC) or standard age-based screening approaches have been conducted. Systematic reviews reported discrimination performances of aggregated five-year concordance indices for Mirai that were generally in the 0.63 to 0.90 range with a median AUC of approximately 0.71, while clinical risk factor–based comparators (breast density alone and traditional risk models including Tyrer-Cuzick, Gail/BCRAT, and the Breast Cancer Surveillance Consortium model [BCSC]) demonstrated a maximum AUC range of 0.54 to 0.69 (median 0.61) as reported by Schopf et al (2024). Lower estimates were reported in demographic and device subgroup analyses as well as sub-analyses excluding individuals who were diagnosed with breast cancer near the index mammogram. Calibration data showed mixed findings, including significant overestimation of risk in the highest decile of Allix5 predictions and overestimation of Mirai-predicted risk across BCSC risk strata in the head-to-head comparison study. There is no direct evidence that the use of these tests improves health outcomes, and indirect evidence is not sufficient to draw conclusions about clinical validity for Allix5. Despite ample literature precedent corroborating clinical validity for the Mirai mammography-based AI risk prediction algorithm, the lack of direct evidence that the use of Mirai improves health outcomes, and no regulatory approval precludes any conclusions regarding the clinical utility. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05968157[a]	MIRAI-MRI: Comparing Screening MRI for Patients at High Risk for Breast Cancer Identified by Mirai and Tyrer-Cuzick	200	Sept 2027

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT07121972	Mirai-MRI: Multi-site Prospective Validation of AI Models for Breast Cancer Risk	400	Jan 2027

NCT: national clinical trial. a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence to review conclusions.

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Radiology

In 2023, the American College of Radiology (ACR) published clinical practice management recommendations for breast cancer screening for women at higher-than-average risk. [29] Regarding risk prediction models that encompass image-based data and artificial intelligence the ACR states "Deep learning models using mammographic images suggest that images contain risk indicators that may not be perceptible to the human eye. In some studies, performance was found to be superior to traditional models, but additional work is needed." Based off their previous recommendations,[30] that emphasized the importance of risk assessment at an age early enough to allow for supplemental screening the ACR makes the following claim "The identification of increasing numbers of genetic mutations, and their associated risks, suggests that risk assessment should take place by age 25 for all women, especially Black women and those of Ashkenazi Jewish descent."

National Comprehensive Cancer Network

The National Comprehensive Cancer Network Guidelines for Breast Cancer Screening and Diagnosis v.1.2026 states the following regarding mammography-based AI algorithms: "Studies with AI image-only based models were found to have a higher median AUC performance (0.72; range, 0.62 to 0.90) compared to breast density models or clinical risk prediction tools such as Gail or Tyrer-Cuzick (0.61; range, 0.54 to 0.69). For an individual ≥35 years of age with a 5-year risk ≥1.7% per the Gail model or as calculated by an imaging-based risk assessment model, the NCCN panel encourages breast awareness and recommends a clinical encounter every 6 to 12 months and annual digital mammography with tomosynthesis, to begin at the age identified as being at increased risk by either model."[31]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Clairity Allix5 (marketed as CLAIRITY BREAST; Clairity, Inc., Boston, MA) is a Software as a Medical Device (SaMD) authorized by the U.S. Food and Drug Administration on May 30, 2025, under De Novo classification DEN240047 (21 CFR 892.8500; product code SEZ; Class II with special controls).[13] It is the first device authorized in a new generic category that FDA defines as a radiological software device to predict future breast cancer risk. Mirai has not been approved or cleared by the US Food and Drug Administration (FDA) and is for research purposes only until authorized by the FDA.

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History

Date	Comments
11/01/26	New policy, approved October 13, 2026, effective for dates of service on or after February 5, 2027, following 90-day provider notification. Policy created with literature review through May 1, 2026. Use of mammography-based AI (artificial intelligence) risk prediction software for individuals undergoing bilateral screening mammography to estimate their 5-year risk of developing breast cancer is considered investigational.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to

the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.