Mammography-based AI (Image-only) Risk Prediction Models

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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers use of mammography-based AI risk prediction software for individuals undergoing bilateral screening mammography to estimate their 5-year risk of developing breast cancer to be **investigational.***

Policy Guidelines

Using more than one mammography-based AI risk prediction model is not indicated to estimate the 5-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 5-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 (eg, ≤10 years) and whether therapeutic interventions would be appropriate and acceptable to the patient.

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 ≥65 years;
- age <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.

Background/Overview

Breast Cancer Risk

Breast cancer is the most commonly diagnosed non-skin cancer in U.S. women and remains a leading cause of cancer death. The American Cancer Society (ACS) estimates the average lifetime risk for a U.S. 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). 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. 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 (BCRAT) and the BCSC calculator are typically used at routine screening encounters to identify women whose 5- or 10-year risk crosses established thresholds for management decisions (i.e., chemoprevention discussion or supplemental imaging). Tyrer-Cuzick (IBIS) and the comprehensive-pedigree models (BRCAPRO, BOADICEA/CanRisk) 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 3 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 3 important limitations. First, individual-level discrimination is modest across all 5 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 5 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 5 models are heterogeneous: only the Gail model and BCSC produce 5-year invasive breast-cancer risk estimates on the scale used by the NCCN ≥1.7% increased risk pathway, and of those 2, only BCSC incorporates mammographic image information (breast density). The remaining 3 models output 10-year, lifetime, or mutation-probability estimates that would not directly support the ≥1.7% 5-year threshold without re-derivation.

The 5-year ≥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. For individuals who meet this threshold and are ≥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 patients. In current practice, this means a 5-year breast-cancer risk estimate ≥1.7%, produced by a tool whose output is calibrated to that horizon (ie, 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[a6]	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	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 FNA with benign breast	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 DCIS

	breast cancer risk. May have limited applicability for extensive family history beyond first-degree relatives.	disease diagnosis if known • BI-RADS breast density (radiologic assessment of the density of the breast tissue by a radiologist who interprets mammograms)		○ Breast augmentation ○ 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 ≥1.67% used to assess eligibility for a risk-reducing agent.	• Age • Age at menarche • Age at first live birth • Family history of breast cancer in first-degree relatives AFAB • Number of previous breast biopsies • Diagnosis of AH	• Validated across multiple studies and cohorts • Accessible online • Available to assess eligibility for a risk-reducing agent • Periodic updates based on changes in breast cancer incidence data • Accounts for competing risks of mortality other than breast cancer	• Performance varies across racial and ethnic subgroups; published recalibrations exist for African American and Asian/Pacific Islander U.S. women, but performance in other groups remains less well characterized • Cannot be used for individuals <35 years of age • Considers only a fraction of family history data: ○ Only includes first-degree relative AFAB (paternal family history excluded) ○ Does not include ages of diagnoses of relatives' breast cancer

				○ Does not include family history of other cancer diagnosis outside breast cancer ○ Does not include mantle radiation • Underestimates risk for development of breast cancer in: ○ Those with germline variants in known breast cancer predisposition genes such as *BRCA1/2* ○ Those with a strong family history of breast cancer ○ Those with a family history of ovarian cancer in the maternal or paternal family lineage ○ Non-white

				individuals ○ Those with AH
International Breast Cancer Intervention Study (IBIS/Tyrer-Cuzick) [8,]	Computerized model base 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 (ie, 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 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: ○ Affected first-, second-, and third-degree (first cousins) relatives ○ Ovarian cancer diagnosis ○ Breast cancer diagnosis in those AMAB ○ Unaffected relatives	• Does not consider risk from mantle radiation • Overestimates risk for development of breast cancer in: ○ Hispanic individuals as this model was validated in primarily White individuals in the United Kingdom ○ AH ○ LCIS ○ Dense breast • Routine clinical use of PRS in risk assessment is not encouraged

			• Periodic updates based on breast cancer incidence data • Accounts for competing risks of mortality other than breast cancer (have to select option) • Incorporates risk estimates from SNPs (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	• 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

	carrier-status modeling.			
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. 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. 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 5-year breast cancer risk prediction from a routine bilateral screening mammogram. The algorithm inputs the 4 standard 2D screening views (RCC, LCC, RMLO, 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 5-year timeframe following the screening mammogram.

Mirai
Mirai is a deep learning model that produces a personalized risk score that generates a 5-year breast cancer risk prediction from a routine bilateral screening mammogram. The algorithm inputs the 4 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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). 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 U.S. Food and Drug Administration (FDA) and is for research purposes only until authorized by the FDA.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

This evidence review addresses the use of mammography-based AI risk prediction software intended to generate a 5-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 5-year risk of individuals who will receive a diagnosis of breast cancer or develop breast cancer within the 5-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.

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, 2 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 5-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 5-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.

Supplemental Information

Practice Guidelines and Position Statements

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. 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, 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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some unpublished 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
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.

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Policy History

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Current Effective Date: 01/01/2027
10/20/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 10/2027

Coding

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Code Type	Code
CPT	19499
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses

coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.