I. Policy

University Health Alliance (UHA) will cover breast imaging when such services meet the medical criteria guidelines (subject to limitations and exclusions) indicated below.

II. Background

Mammography is the only screening test proven to reduce all-cause mortality in women who undergo the testing appropriately. Although mammography is an effective screening tool, it does have limitations, especially in women with dense breasts. New imaging techniques are being developed to overcome these limitations, enhance cancer detection, and improve patient outcome. Digital mammography, computer-aided detection (CAD), breast ultrasound, and breast magnetic resonance imaging (MRI) are frequently used adjuncts to mammography in today's clinical practice and are covered services within the limitations and exclusions below, but their utility in decreasing breast cancer mortality or avoiding unnecessary operations is unproven. Some advanced testing is known to be counterproductive and for these reasons, careful application is very important.

III. Criteria/Guidelines

A. UHA considers mammography and the following adjuncts to be medically necessary (subject to limitations and exclusions) within the following indications:

1. The U.S. Preventive Services Task Force recommends biennial screening mammography as a preventive service for women aged 50 to 74. UHA benefits will cover annual screening mammograms for women ages 40 and older as per the UHA medical benefits guide.
   a. The decision to start screening mammography in women prior to age 50 years should be an individual one. For women who are at average risk for breast cancer, most of the benefit of mammography results from biennial screening during ages 50 to 74 years.
   b. Women who have preexisting breast cancer or a previously diagnosed high-risk breast lesion, who are at high risk for breast cancer because of a known underlying genetic mutation (such as a BRCA1 or BRCA2 gene mutation or other familial breast cancer syndrome), who have a history of chest radiation at a young age, or have a parent, sibling, or child with breast cancer are at higher risk for breast cancer and thus may benefit from more frequent or earlier screening.
   c. Screening mammography for men does not meet criteria for medical necessity. Current guidelines from the U.S. Preventive Services Task Force and the American College of Radiology recommend such screening only for women.


3. Diagnostic mammography for all members with signs or symptoms of breast disease or history of breast cancer.

4. Digital mammography as an acceptable alternative to film mammography:
   a. Digital mammography is more sensitive than film mammography for dense breasts and is preferred, when available, for women with increased breast density.

B. UHA considers Computer-aided detection (CAD) medically necessary as an adjunct to mammography.
1. Computer-aided detection (CAD) of malignancy with MRI of the breast is not considered medically necessary because its clinical value has not been established.

2. Computer Aided Detection (CAD) of malignancy with Ultrasound is not considered medically necessary because its clinical value has not been established.

C. UHA considers breast ultrasound medically necessary as an aid for radiologists to localize breast lesions and in guiding placement of instruments for cyst aspiration and percutaneous breast biopsies.

D. UHA considers magnetic resonance imaging (MRI), with or without contrast materials, of the breast medically necessary for members who have had a recent (within the past year) conventional mammogram and/or breast sonogram, in any of the following circumstances where MRI of the breast may affect their clinical management:

1. For the evaluation of equivocal findings on conventional imaging with mammography and ultrasound, such as focal asymmetry or a mammographic abnormality seen on only one view; or

2. For individuals who received radiation treatment to the chest between ages 10 and 30 years, such as for Hodgkin disease and Wilms’ tumors; or

3. To assess tumor location, size, and extent before and/or after neoadjuvant chemotherapy in persons with locally advanced breast cancer for determination of eligibility for breast conservation therapy; or

4. To detect silicone implant rupture in symptomatic members. There is no role for breast MRI imaging to detect rupture of saline implants, as rupture results in rapid deflation of the implant and is easily detected on physical examination and/or mammography; or

5. To detect suspected local tumor recurrence in members with breast cancer who have undergone mastectomy and/or breast reconstruction with an implant; or

6. For breast cancer patients treated with breast conserving therapy to differentiate surgical scarring and radiation changes from breast cancer recurrence in cases where the physical examination and imaging with mammography and/or ultrasound is difficult to interpret; or

7. To detect local tumor recurrence in individuals with breast cancer who have radiographically dense breasts or old scar tissue from previous breast surgery that compromises the ability of combined mammography and ultrasonography; or

8. To detect the extent of residual cancer in the recently post-operative breast with positive pathological margins after incomplete lumpectomy when the member still desires breast conservation and local re-excision is planned; or

9. To evaluate persons with lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS); or

10. To guide localization of breast lesions to perform needle biopsy when suspicious lesions exclusively detected by contrast-enhanced MRI cannot be visualized with mammography or ultrasonography; or

11. To localize the site of primary occult breast cancer in individuals with adenocarcinoma suggestive of breast cancer discovered as axillary node metastasis or distant metastasis; or

12. To map the extent of primary tumors and identify multi-centric disease in persons with localized breast cancer (stage I or II, T0-1 N0-1 M0) prior to surgery (lumpectomy versus mastectomy).

E. MRI has higher sensitivity for the detection of breast cancer in the high risk population than mammography or ultrasound and thus is recommended for screening women who are at significantly high risk (lifetime risk 20 percent or higher) for the development of breast cancer. UHA considers breast
MRI a medically necessary adjunct to mammography for screening of women considered to be at high genetic risk of breast cancer because of any of the following:

1. Carry or have a first-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes); or
2. Confirmed presence of BRCA1 or BRCA2 mutation; or
3. First degree blood relative with BRCA1 or BRCA2 mutation and are untested; or
4. Who received chest irradiation, such as mantle radiation for Hodgkin lymphoma; or
5. Sufficiently strong family histories of breast and/or ovarian cancer; or
6. Have a lifetime risk of breast cancer of 20 to 25% or more using standard risk assessment models (BRCAPRO, Claus model, Gail model, or Tyrer-Cuzick).

F. Bilateral dual-energy (DE) contrast-agent-enhanced (CE) digital mammography may be medically necessary as an adjunct for patients for whom MRI is medically necessary (see above) but who cannot undergo MRI evaluation (e.g., claustrophobic, pacemaker), as studies have shown comparable sensitivity.

G. UHA considers Digital Breast Tomosynthesis (DBT) medically necessary subject to the limitations below:

1. DBT for breast cancer screening is covered in conjunction with digital screening mammography within the guidelines for mammography found in the UHA medical benefits guide.
2. DBT for breast cancer diagnostics is covered for classification of masses, distortions, and asymmetries.

### IV. Limitations & Exclusions

The following breast imaging indications, modalities, and adjuncts are not considered medically necessary because there is insufficient scientific evidence of clinical benefit vs potential harm. UHA encourages providers to inform patients of the financial implications of choosing to have the breast imaged within any of the following circumstances:

A. UHA does not consider routine supplemental imaging for women with dense breasts medically necessary. Approximately one-half of women undergoing screening mammography have dense breasts. Implementing supplemental screening after negative mammography in women with dense breasts would expose a great many women to potential false-positive screening results with associated anxiety and need for breast biopsy, and there is no direct evidence that such screening affects mortality from breast cancer.

B. UHA does not consider breast MRI medically necessary for any indications other than listed above (section II), including any of the following:

1. To confirm implant rupture in symptomatic individuals whose ultrasonography shows rupture, especially with implants more than 10 years old (ultrasound sufficient to proceed with removal); or
2. To differentiate benign from malignant breast disease, especially clustered micro-califications; or
3. To differentiate cysts from solid lesions (ultrasound indicated); or
4. To evaluate breasts before biopsy in an effort to reduce the number of surgical biopsies for benign lesions; or
5. Surveillance of asymptomatic individuals with breast cancer who have completed primary therapy and who are not at high genetic risk of breast cancer; or
6. To provide an early prediction of response to adjuvant breast cancer chemotherapy in guiding choice of chemotherapy regimen; or

7. Dermatomyositis as an indication for use of MRI for breast cancer screening; or

8. To screen for breast cancer in members with average risk of breast cancer; or

9. To screen BRCA-positive men; or

10. As a substitute for or adjunct to mammography in women with known dense breast tissue; or

11. To evaluate patients with breast pain or patients with palpable lumps who have had normal mammography and sonography.

C. Breast Ultrasound (sonography) is not covered for routine breast cancer screening including patients with dense breast tissue because clinical evidence has not yet demonstrated that routine use of ultrasonography as an adjunct to screening mammography reduces the mortality rate from breast cancer. High frequency breast ultrasound is covered for the evaluation/characterization of known breast abnormalities.

D. UHA does not consider the following breast imaging modalities medically necessary because of insufficient evidence of efficacy:

   1. Xeroradiography for breast
   2. Contrast-enhanced spectral mammography
   3. Diffusion weighted imaging
   4. Breast-specific gamma imaging (BSGI), positron emission tomography (PET) scanning, and positron emission mammography (PEM) Thermography (including digital infrared thermal imaging, magnetic resonance (MR) thermography and temperature gradient studies) for the detection of breast cancer Transillumination (light scanning or diaphanography) of the breast for detecting breast cancer
   5. Electrical impedance scanning (EIS) of the breast to distinguish benign from malignant breast lesions or the effectiveness of EIS of the breast elastography by any method (i.e., ultrasound or magnetic resonance)
   6. Breast Specific Gamma Imaging (Scintimammography) for breast cancer screening or diagnosis
   7. Molecular breast imaging (MBI) techniques for supplemental screening in women with dense breasts and negative mammography

**NOTE:**
This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or members’ individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.
V. Administrative Guidelines

A. Prior authorization is not required.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Descriptions</th>
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<tbody>
<tr>
<td>0159T</td>
<td>Computer aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI</td>
</tr>
<tr>
<td>0346T</td>
<td>Ultrasound, elastography (List separately in addition to code for primary procedure) 0422T Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral</td>
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<tr>
<td>76377</td>
<td>3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; requiring image post-processing on an independent workstation</td>
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<tr>
<td>76498</td>
<td>Unlisted magnetic resonance procedure (eg, diagnostic, interventional)</td>
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<tr>
<td>76499</td>
<td>Unlisted diagnostic radiographic procedure</td>
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<tr>
<td>76641</td>
<td>Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete</td>
</tr>
<tr>
<td>76642</td>
<td>Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited</td>
</tr>
<tr>
<td>77051</td>
<td>Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further review for interpretation, with or without digitization of film radiographic images; diagnostic mammography (List separately in addition to code for primary procedure)</td>
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<tr>
<td>77052</td>
<td>Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further review for interpretation, with or without digitization of film radiographic images; screening mammography (List separately in addition to code for primary procedure)</td>
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<tr>
<td>77055</td>
<td>Mammography; unilateral</td>
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<tr>
<td>77056</td>
<td>Mammography; bilateral</td>
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<td>77057</td>
<td>Screening mammography, bilateral (2-view study of each breast)</td>
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<tr>
<td>77058</td>
<td>Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral</td>
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<tr>
<td>77059</td>
<td>Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral</td>
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<tr>
<td>77061</td>
<td>Digital breast tomosynthesis; unilateral</td>
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<tr>
<td>77062</td>
<td>Digital breast tomosynthesis; bilateral</td>
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<tr>
<td>77063</td>
<td>Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)</td>
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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Descriptions</th>
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<tr>
<td>G0202</td>
<td>Screening mammography, producing direct digital image, bilateral, all views</td>
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<tr>
<td>G0204</td>
<td>Diagnostic mammography, producing direct digital image, bilateral, all views</td>
</tr>
<tr>
<td>G0206</td>
<td>Diagnostic mammography, producing direct digital image, unilateral, all views</td>
</tr>
<tr>
<td>G0279</td>
<td>Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to G0204 or G0206)</td>
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<tr>
<td>S8080</td>
<td>Scintimammography (radioimmunosintigraphy of the breast), unilateral, including supply of radiopharmaceutical</td>
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VI. Policy History

Policy Number: MPP-0122-160801

Current Effective Date: 01/01/2018
Original Document Effective Date: 08/01/2016
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PAP Approved Date: 06/21/2016