High-Risk Benign Breast Lesions

Recommendations Report

November 2025

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Background

High-risk benign breast lesions are histologic abnormalities that are associated with an increased risk of breast cancer (1). Appropriate management of such lesions can help to reduce breast cancer incidence by preventing progression to invasive disease, and/or identifying situations where concurrent in situ or invasive cancer exists (1). However, the lack of consensus regarding the management of such lesions on a biopsy has led to variation in care of these patients (2).

The need for consistent management recommendations for high-risk benign breast lesions specific to the Ontario context was identified by the Ontario Health (Cancer Care Ontario) (OH-CCO) Breast Cancer Pathway Map Working Group and Breast Cancer Advisory Committee. A multidisciplinary working group was formed to develop recommendations for the management of high-risk benign breast lesions in Ontario. Working group members represented healthcare professionals who care for patients with breast lesions, including radiology, pathology, surgical oncology, medical oncology, and genetic counselling. Upon review of the Cancer Care Ontario Breast Cancer Screening and Diagnosis Pathway Maps, the working group included the following high-risk benign breast lesions in this recommendations report: atypical ductal hyperplasia (ADH), mucocele-like lesions (MLL), papillary lesions, radial scars/complex sclerosing lesions, atypical lobular hyperplasia (ALH), lobular carcinoma in situ (LCIS), columnar cell change, flat epithelial atypia, fibroepithelial lesions with increased stromal cellularity, spindle cell lesions/mesenchymal lesions, and microglandular adenosis (MGA).

A systematic review of the evidence on management and follow-up strategies for high-risk breast lesions was conducted in 2018, and an updated literature review was conducted in 2022. After that, more recently published guidance documents were identified and reviewed (3,4). The working group developed recommendations based on the collated evidence as well as working group members' expertise. The document was reviewed by the working group, OH-CCO disease site groups (e.g., the Ontario Breast Cancer Advisory Committee), relevant program leadership and representatives, and additional clinical experts from across Ontario and Canada (see Appendix). The recommendations included in the report are relevant to surgeons, oncologists, primary care providers, radiologists, and pathologists with a special interest in breast cancer.

High-Risk Benign Breast Lesion Recommendations

Overarching Principles

Identification of High-Risk Lesions, Risk Assessment, and Breast Cancer Screening

Individuals with high-risk lesions are eligible for annual breast cancer screening as per Ontario Breast Screening Program (OBSP) recommendations (see <u>Breast Screening Recommendations Summary | Cancer Care Ontario</u>). These individuals should also receive a breast cancer risk assessment and counselling about breast cancer risk reduction options. Individuals with a significant family history of cancer may have this assessment performed as part of the High Risk Ontario Breast Screening Program (see <u>Referral Guidance for Hereditary Cancer Genetic Assessment</u>). If individuals have increased risk based on the presence of high-risk lesions, then the risk assessment can be performed by a clinician with expertise in this area (see <u>My CancerIQ Breast Cancer Assessment</u> and the <u>Breast Cancer Prevention Pathway Map</u>). However, in the absence of family history or genetic risk factors, high-risk lesions alone do not qualify patients for the High Risk Ontario Breast Screening Program.

Referral to General Surgeon versus Breast Surgeon

In Ontario, breast surgery, including cancer surgery, is performed by general surgeons as well as surgeons who specialize in the treatment of breast disorders. In this document, where surgical referral is indicated, referral to a general surgeon or breast surgical specialist is acceptable. For certain rare diagnoses, referrals to a specialized breast pathologist and surgeon are warranted. Practitioners with any ongoing uncertainty regarding a high-risk lesion after having reviewed this guideline are advised to make a referral to a surgeon for assessment. The purpose of the surgical consultation is to have the individual's imaging reviewed, along with a discussion surrounding upgrade rate of the lesion being assessed, balanced with patient preference for care.

Role of Vacuum-Assisted Breast Biopsy (VAB) or Vacuum-Assisted Excision (VAE)

VAB/VAE is often used as a tool in breast diagnosis, and some guidelines have incorporated this in the routine evaluation of breast lesions (5). However, access to this is not standard in Ontario. Thus, surgical excision remains the preferred procedure when indicated.

Role of MRI and Contrast Enhanced Mammography (CEM) in the Evaluation of High-Risk Lesions

There is variability in access to MRI and CEM in the evaluation of breast lesions. The possible indications for these tests are considered for the relevant diagnoses. Consider contrast imaging when there is high concern for malignancy or when not excised.

Assessment of Radiologic-Pathologic Concordance

The importance of assessing radiologic-pathologic concordance in the management of high-risk benign breast lesions should be emphasized (6). Determining if the biopsy result is representative of the imaging abnormality guides further treatment, including the need for additional biopsy, excision, and appropriate radiologic follow-up. Surgical excision of benign high-risk lesions is recommended when there is radiologic-pathologic discordance or when the risk of upgrade to malignant diagnosis is considered too high to follow with conservative imaging.

Discussion of Endocrine Prevention (Chemoprevention) in Patients with High-Risk Breast Lesions

Depending on institutional practice, the surgeon may be the only clinician broaching the topic of endocrine prevention with tamoxifen, low-dose tamoxifen, or aromatase inhibitor with patients at elevated risk of developing breast cancer. A systematic review of the risks and benefits of endocrine prevention falls outside the objectives of this report. If the patient is appropriate for this discussion, and the clinician does not feel comfortable, a referral to a medical oncologist for discussion of endocrine prevention is recommended (7,8).

Lesion-Specific Recommendations

Atypical Ductal Hyperplasia (ADH)

Upgrade Rate¹ at Excision: 7-52.9% (9-55)

Recommendations:

- Excision recommended, refer to a surgeon (although not every case requires excision, see considerations below). Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.
- If excised, proceed to annual screening after excision. Individuals with high-risk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).
- If after consultation with a surgeon, the decision was made **not to excise**, follow for 2 years, with follow-up at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.
- Provide breast cancer risk assessment and counselling about breast cancer risk reducing options (i.e., endocrine prevention, see above).
- Pathologists should specify the extent of ADH in the specimen (focal or incidental vs. present on multiple cores, vs. prominent with differential of low-grade ductal carcinoma in situ).

Considerations:

- Some ADH may not require excision. The factors to be considered for observation (44,56–59):
 - Characteristics/distribution of mammographic calcifications (i.e., presence of more benign appearing microcalcifications without any associated mass/distortion)
 - Smaller lesion size on imaging resulting in complete or near complete removal of calcifications on post-biopsy imaging
 - Larger sample size (i.e., biopsy using vacuum-assisted biopsy where the majority of lesion is sampled)
 - o Small volume of ADH in the core needle biopsy specimen as described by pathologist
 - Absence of additional high-risk lesions (i.e., any other high-risk lesions outlined in this document)

¹ Upgrade rate is defined as the likelihood that the lesion is under-sampled at biopsy and actually contains an in situ or invasive cancer. The upgrade rates presented in this report represent ranges found in the literature, rather than pooled averages. The 'Resource Guide: Surgical Management of Benign or High-Risk Lesions' from the American Society of Breast Surgeons (ASBrS) discusses many of the high-risk benign breast lesions included in this report (3). The ASBrS guide uses a different methodology, which presents pooled meta-analysis percentages. As a result, many of the upgrade rates presented in the ASBrS guide will be lower than those presented in this report.

Mucocele-Like Lesions (MLL)

Upgrade Rate at Excision: 0-17% (60–69)

Recommendations:

- Referral to a surgeon for consultation is recommended. Routine excision is not required if
 pathology is concordant with radiology assessment. Excision should be discussed in context of
 patient preference and radiologic risk factors.
- Risk of upstaging to mucinous carcinoma is higher where the biopsy shows atypia, therefore, MLL with atypia should undergo excision, and those without atypia, do not routinely require excision.
- If excised, proceed to annual screening after excision. Individuals with high-risk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).
- If unexcised, follow for 2 years, with follow-up at 6, 12, and 24 months using the imaging modality
 with which it was originally seen (ordered by the referring physician), then proceed to annual
 screening.
- Pathologists should specify whether the lesion was examined on additional levels.

Considerations

• Excision recommended for MLL with atypia as the upgrade rate to breast cancer is as high as 31% (61,63,69).

Pure Papillary Lesions

Upgrade Rate at Excision (pure papillary lesions with atypia): 18.7-56.5% (70-74)

Upgrade Rate at Excision (pure papillary lesions without atypia): 0-14.3% (70-74)

PURE PAPILLARY LESIONS WITH ATYPIA

- Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.
- If *excised*, proceed to annual screening after excision. Individuals with high-risk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).
- If after consultation with a surgeon, the decision was made **not to excise**, follow for 2 years, with follow-up at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.
- Provide breast cancer risk assessment and counselling about breast cancer risk reducing options (i.e., endocrine prevention).
- Pathologists should comment on the extent of atypia (i.e. papilloma involved by ADH, at least ADH, as opposed to the entire lesion being atypical).

PURE PAPILLARY LESIONS WITHOUT ATYPIA

Recommendations:

- Referral to a surgeon for consultation is recommended. Routine excision is not required if
 pathology is concordant with radiology assessment. Excision should be discussed in context of
 patient preference and radiologic risk factors.
- If **excised** (i.e., based on patient preference or imaging discordance), proceed to annual screening after excision.
- If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the
 imaging modality with which it was originally seen (ordered by the referring physician), then
 proceed to average risk screening.
- Pathologically incidental papillary lesions without atypia, defined as small papillary lesions seen on biopsy away from the targeted radiologic abnormality, do not require follow-up. Only the index lesion that prompted the biopsy requires follow-up according to the recommendations for that lesion.

Considerations:

- Some papillary lesions without atypia may be considered for excision. This shared decision-making between surgeon and patient will consider patient preference. The factors to be weighed in the consideration of excision include:
 - >54 years of age (75)
 - Lesions >1 cm at largest diameter (75,76)
 - Lesions with dynamic change in size (>5 mm growth in max diameter in 6 months) (4)
 - Associated ipsilateral breast cancer (consensus)
 - If presence of associated high-risk lesion on excision will alter management (e.g., offer chemoprevention) (7)
 - o Radiologic-pathologic discordance (76)
 - Symptoms interfering with perceived quality of life (e.g., bloody nipple discharge, palpable mass) (3,4,77)
- The American Society of Breast Surgeons recommends surgical excision for symptomatic papillary lesions irrespective of atypia (3).
- For these asymptomatic lesions <1cm with adequate sampling (i.e., vacuum-assisted biopsy or extensive sampling of lesion) and radiologic-pathologic concordance, 6-month imaging follow-up rather than referral can be considered. This should be decided based on institutional guidelines.

Pure Radial Scars/Complex Sclerosing Lesions

Upgrade Rate at Excision (all pure radial scars/complex sclerosing lesions): 0-25.0% (12,15,18,22,24,28,29,43,51,78–104)

PURE RADIAL SCARS/COMPLEX SCLEROSING LESIONS WITH ATYPIA

- Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.
- If excised, proceed to annual screening after excision. Individuals with high-risk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).

- If after consultation with a surgeon, the decision was made not to excise, follow for 2 years, with follow-up at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.
- Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.

PURE RADIAL SCARS/COMPLEX SCLEROSING LESIONS WITHOUT ATYPIA

Recommendations:

- Referral to a surgeon for consultation is recommended. Routine excision is not required if
 pathology is concordant with radiology assessment. Excision should be discussed in context of
 patient preference and radiologic risk factors.
- If excised, proceed to average risk screening after excision.
- If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the
 imaging modality with which it was originally seen (ordered by the referring physician), then
 proceed to average risk screening. Follow-up at 6 months can be considered according to
 institutional practice.
- Pathologically incidental radial scars/complex sclerosing lesions without atypia reported in the biopsy sample, performed to diagnose the targeted radiologic abnormality, do not require followup. Only the index lesion requires follow-up according to the recommendations for that lesion.

Considerations:

- If atypia is present, the rate of upgrade is as high as 35% (51) and therefore excision of radial scar/complex sclerosing lesion WITH atypia is recommended.
- Some pure radial scars/complex sclerosing lesions without atypia may require excision. The factors to be considered for excision include:
 - o Family history of breast or ovarian cancer (105,106)
 - Associated with a mass (107,108)
 - o Radiologic-pathologic discordance (107,109)
- Incidental radial scars/complex sclerosing lesions without atypia should be managed as if they were the index lesion, with referral to a surgeon for consultation, unless the radial scar/complex sclerosing lesion is very small in size (<5mm) and concordant.

Atypical Lobular Hyperplasia (ALH)

Upgrade Rate at Excision: 1.7-36% (12,14,15,18,21,22,24,25,28-30,32,33,43,78,80,81,88,94,105-130)

- Referral to a surgeon for consultation is recommended. Generally, ALH does not require excision if breast imaging has ruled out any other lesions and is reported as concordant. Excision should be discussed in context of patient and radiologic risk factors.
- If *excised*, proceed to annual screening after excision. Individuals with high-risk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).
- If *unexcised* and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.

- Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.
- Pathologically incidental ALH, defined as lesions noted in an area unrelated to the targeted radiologic abnormality, do not require short interval follow-up. Only the index lesion that prompted the biopsy requires follow-up according to the recommendations for that lesion.

Considerations:

- Referral to a surgeon for consideration of excision is recommended if additional risk factors are present, including:
 - o Family history of breast or ovarian cancer (105,106)
 - Associated with a mass (107,108)
 - Associated with other high-risk lesions such as ADH and non-classic LCIS (131,132)
 - o Radiologic-pathologic discordance (107,109,111,131)
- Consider bilateral contrast enhanced imaging for patients with ALH prior to surgical consultation due to associated increased risk of bilateral malignancy.
- Pathologists should report the presence of calcifications and whether they are associated with the target lesion, as this may guide management, through consultation between surgeon and radiologist.

Classic Lobular Carcinoma in Situ (LCIS)

Upgrade Rate at Excision: 1.7-36% (12,15,18,21,22,24,26,28–30,33,43,78,80,81,88,94,105–107,109–130,133,134)

CLASSIC LOBULAR CARCINOMA IN SITU

Recommendations:

- Referral to a surgeon for consultation is recommended. Generally, classic LCIS does not require
 excision if breast imaging has ruled out any other lesions and is reported as concordant. Excision
 should be discussed in context of patient and radiologic risk factors.
- The American Society of Breast Surgeons' 'Resource Guide: Surgical Management of Benign or High-Risk Lesions' reports an upstage rate of 0-4% in cases where there is concordance between radiologist and pathologist (3).
- If *excised* for definitive diagnosis, proceed to annual screening after excision. Individuals with highrisk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).
- If *unexcised* and no growth or change, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.
- Provide breast cancer risk assessment and counselling about breast cancer risk reducing options (ALH and classic LCIS are non-obligate precursor lesions, implying the presence of either denotes an increased risk of cancer in either breast in the order of 1-1.5% per year) (3).

Considerations:

• It is not routine practice in Ontario to quantify the amount of classic LCIS in a core biopsy, and it is suggested that educational initiatives should be considered for this guidance document.

- Pathologists should report the presence of calcifications and whether they are associated with the target lesion, as this may guide management, through consultation between surgeon and radiologist.
- Referral to a surgeon for consideration of excision is recommended if additional risk factors are present, including:
 - Extensive LCIS involving >4 terminal ductal lobular units (107)
 - Associated with other high-risk lesions such as ADH and non-classic LCIS (131,132)
 - o Radiologic-pathologic discordance (107,111,115,131)
- Consider bilateral contrast enhanced imaging for patients with classic LCIS prior to surgical consultation due to associated increased risk of bilateral malignancy.
- Referral to genetic counselling is recommended for patients with a family history of breast cancer if appropriate based on current provincial guidelines (30).

VARIANT/NON-CLASSIC LOBULAR CARCINOMA IN SITU (PLEOMORPHIC OR FLORID)

Recommendations:

- Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.
- If excised, proceed to annual screening after excision. Individuals with high-risk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).
- If there is no growth, and after consultation with a surgeon, the decision was made **not to excise**, follow for 2 years, with follow-up at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.
- Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.

Considerations:

• Consider bilateral contrast enhanced imaging for patients with variant/non-classic LCIS prior to surgical consultation due to associated increased risk of bilateral malignancy.

Columnar Cell Change

FLAT EPITHELIAL ATYPIA (COLUMNAR CELL CHANGE WITH ATYPIA)

Upgrade Rate at Excision: 0-18.3% (9,12,14–16,18,21,28,29,31,40,43,45,81,135–155)

- Referral to a surgeon for consultation is recommended. Routine excision is not required if
 pathology is concordant with radiology assessment. Excision should be discussed in context of
 patient preference and radiologic risk factors.
- If excised, proceed to annual screening after excision. Individuals with high-risk lesions should have annual screening as per OBSP recommendations (see Breast Screening Recommendations Summary | Cancer Care Ontario).
- If *unexcised* and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.
- Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.

Considerations:

- Referral to a surgeon for consideration of excision is recommended if additional risk factors are present, including:
 - o Presence of ADH or ALH (135,136,138,141,147,156,157)
 - Presence of residual calcifications post-core biopsy or extensive calcifications if not adequately sampled (15,135,139,142–144,146) such that concordance with pathology is not clear
 - Quality of the core needle excision (138) insufficient for definitive diagnosis
 - Radiologic-pathologic discordance (consensus)
- Pathologists should report the presence of calcifications and whether they are associated with the target lesion, as this may guide management, through consultation between surgeon and radiologist.
- Referral to genetic counselling can be considered, if appropriate, in patients with a family history of breast cancer (140).

COLUMNAR CELL CHANGE WITHOUT ATYPIA

Recommendations:

 Follow-up at 12 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.

Considerations:

 The opinion of the working group is that this lesion is benign. A 12-month follow-up study should be considered if the subject is not receiving annual screening. Follow-up should only be considered if there is discordance with pathology and imaging.

Fibroepithelial Lesions with Increased Stromal Cellularity

Upgrade Rate at Excision: 7.7-29% (158–165)

Recommendations:

- Referral to a surgeon for consultation is recommended. Routine excision is not required if
 pathology is concordant with radiology assessment. Excision should be discussed in context of
 patient preference and radiologic risk factors.
- If excised, proceed to average risk screening after excision.
- If *unexcised* and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.

Considerations:

- The following factors may be considered when evaluating for excision, however, the working group did not reach consensus on which of the following would support a recommendation of excision:
 - O Heterogeneous echotexture, lack of internal vascularity, and high BIRADS® score (≥4b)
 (159)

- Fibroepithelial lesions where phyllodes tumors cannot be ruled out on pathology (given that phyllodes and fibroadenoma cannot always be resolved confidently on the needle core specimen alone) (158)
- Patients with lesions >2 cm that are potentially new or growing (consensus)
- o Radiologic-pathologic discordance (consensus)

Spindle Cell Lesions/Mesenchymal Lesions

Spindle cell lesions of the breast include both benign and malignant diagnoses that may be challenging to classify (166). Management of the benign lesions depends on the pathologic subclassification.

Recommendations:

- Obtain pathology review of core biopsy by expert breast or soft tissue pathologist with capacity to perform appropriate immunohistochemical analysis.
- Excision recommended, refer to a breast surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.
- If *excised*, proceed to annual screening or follow-up according to final diagnosis (determined by surgeon, depending on diagnosis of soft tissue sarcoma versus benign mesenchymal lesion).

Considerations:

These cases require expert pathology review and involvement of a specialized breast surgeon.

Microglandular Adenosis (MGA)

MGA is a rare benign lesion that mimics invasive triple negative breast cancer (167). The working group felt that, although rare, it was important to include this lesion because of the potential for misclassification.

- Obtain pathology review of core biopsy by expert breast pathologist.
- Excision recommended if there is any question as to whether the lesion harbours malignancy, refer to a breast surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.
- If excised, proceed to average risk screening or follow-up according to final diagnosis.
- Pathologists need to clarify whether MGA is incidental or predominant lesion. Conservative
 management can be considered in former. Radiologic-pathologic correlation should help drive the
 management.
- Pathologists should report any form of atypia, either cytologic, architectural, or mitotic activity.
- Excision is recommended for atypical MGA due to its association with triple negative breast carcinoma.

Sample Language for Management Guidance in Pathology and Breast Imaging Reports

Atypical Ductal Hyperplasia

Referral to a surgeon for excision is recommended. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.

Mucocele-Like Lesions

Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.

If unexcised, follow for 2 years, with follow-up at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.

Pure Papillary Lesions with Atypia

Referral to a surgeon for excision is recommended. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.

Pure Papillary Lesions without Atypia

Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.

If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening.

Pure Radial Scars/Complex Sclerosing Lesions with Atypia

Referral to a surgeon for excision is recommended. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.

Pure Radial Scars/Complex Sclerosing Lesions without Atypia

Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.

If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.

Atypical Lobular Hyperplasia

Referral to a surgeon for consultation is recommended. Generally, ALH does not require excision if breast imaging has ruled out any other lesions and is reported as concordant. Excision should be discussed in context of patient and radiologic risk factors.

If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.

Classic Lobular Carcinoma in Situ

Referral to a surgeon for consultation is recommended. Generally, classic LCIS does not require excision if breast imaging has ruled out any other lesions and is reported as concordant. Excision should be discussed in context of patient and radiologic risk factors.

If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.

Variant/Non-Classic Lobular Carcinoma in Situ

Referral to a surgeon for excision is recommended. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.

Flat Epithelial Atypia (Columnar Cell Change with Atypia)

Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.

If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.

Columnar Cell Change without Atypia

Follow-up at 12 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.

Fibroepithelial Lesions with Increased Stromal Cellularity

Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.

If unexcised and no growth, follow for 2 years, with follow-up at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.

Spindle Cell Lesions/Mesenchymal Lesions

Referral to a breast surgeon for excision is recommended. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.

Microglandular Adenosis

Referral to a breast surgeon for excision is recommended if there is any question as to whether the lesion harbours malignancy. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.

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Appendix: Summary of Recommendations

Summary of High-Risk Benign Breast Lesion Management Recommendations

Lesion	Initial Management	Follow-Up
Atypical Ductal Hyperplasia	Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making. Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.	If excised, proceed to annual screening after excision. If unexcised, follow for 2 years at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.
Mucocele-Like Lesions	Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.	If excised, proceed to annual screening after excision. If unexcised, follow for 2 years at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.
Pure Papillary Lesions with Atypia	Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making. Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.	If excised, proceed to annual screening after excision. If unexcised, follow for 2 years at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.

Lesion	Initial Management	Follow-Up
Pure Papillary Lesions without Atypia	Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.	If excised, proceed to annual screening after excision. If unexcised and no growth, follow for 2 years at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening.
Pure Radial Scars/Complex Sclerosing Lesions with Atypia	Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making. Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.	If excised, proceed to annual screening after excision. If unexcised, follow for 2 years at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.
Pure Radial Scars/Complex Sclerosing Lesions without Atypia	Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.	If excised, proceed to average risk screening after excision. If unexcised and no growth, follow for 2 years at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.

Lesion	Initial Management	Follow-Up
Atypical Lobular Hyperplasia	Referral to a surgeon for consultation is recommended. Generally, ALH does not require excision if breast imaging has ruled out any other lesions and is reported as concordant. Excision should be discussed in context of patient and radiologic risk factors. Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.	If excised, proceed to annual screening after excision. If unexcised and no growth, follow for 2 years at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.
Classic Lobular Carcinoma in Situ	Referral to a surgeon for consultation is recommended. Generally, classic LCIS does not require excision if breast imaging has ruled out any other lesions and is reported as concordant. Excision should be discussed in context of patient and radiologic risk factors. Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.	If excised, proceed to annual screening after excision. If unexcised and no growth or change, follow for 2 years at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.
Variant/Non- Classic Lobular Carcinoma in Situ	Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making. Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.	If excised, proceed to annual screening after excision. If unexcised, follow for 2 years at 6, 12, and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening.

Lesion	Initial Management	Follow-Up
Flat Epithelial Atypia (Columnar Cell Change with Atypia)	Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors. Provide breast cancer risk assessment and counselling about breast cancer risk reducing options.	If excised, proceed to annual screening after excision. If unexcised and no growth, follow for 2 years at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to annual screening. Follow-up at 6 months can be considered according to institutional practice.
Columnar Cell Change without Atypia	N/A	Follow-up at 12 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.
Fibroepithelial Lesions with Increased Stromal Cellularity	Referral to a surgeon for consultation is recommended. Routine excision is not required if pathology is concordant with radiology assessment. Excision should be discussed in context of patient preference and radiologic risk factors.	If excised, proceed to average risk screening after excision. If unexcised and no growth, follow for 2 years at 12 and 24 months using the imaging modality with which it was originally seen (ordered by the referring physician), then proceed to average risk screening. Follow-up at 6 months can be considered according to institutional practice.
Spindle Cell Lesions/ Mesenchymal Lesions	These cases require expert pathology review and involvement of a specialized breast surgeon. Excision recommended, refer to a surgeon. Decision to excise will be made with the patient, considering comorbidities and patient preference in shared decision-making.	If excised, proceed to annual screening or follow-up according to final diagnosis.

Lesion Initial Mana	gement	Follow-Up
Microglandular Adenosis Dotain path biopsy by expathologist. Excision recommany question lesion harbot to a breast sexcise will be patient, con	ology review of core spert breast ommended if there is a sto whether the burs malignancy, refer surgeon. Decision to e made with the sidering comorbidities preference in shared	If excised, proceed to average risk screening or follow-up according to final diagnosis.

Appendix: Acknowledgements

Ontario Health (Cancer Care Ontario) would like to acknowledge the contribution and expertise of the High-Risk Benign Breast Lesions Working Group and external expert reviewers.

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