MEDICAL POLICY

SUBJECT: PERCUTANEOUS BREAST BIOPSY

POLICY NUMBER: 6.01.04
CATEGORY: Technology Assessment

EFFECTIVE DATE: 11/19/99
REVISED DATE: 07/19/01
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- If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
- Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
- Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer-reviewed literature, the use of percutaneous breast biopsy systems (e.g., ABBI®, ATEC®, EnCor™, Mammothome®, SiteSelect®, and Vacora® systems) that have been approved by the U.S. Food and Drug Administration (FDA) have been medically proven to be effective and therefore, may be considered medically appropriate alternatives for diagnostic evaluation of nonpalpable breast abnormalities.

II. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous breast biopsy systems have not been medically proven to be effective and therefore, are considered not medically necessary when used for therapeutic purposes; such as complete excision of a lesion or lumpectomy.

III. Based upon our criteria and assessment of the peer-reviewed literature, stereotactic or ultrasonic localization of nonpalpable breast lesions has been medically proven to be effective and therefore, medically appropriate for patients undergoing percutaneous biopsy of nonpalpable breast lesions.

IV. Based upon our criteria and assessment of the peer-reviewed literature, stereotactic localization for palpable breast lesions or in patients with nonpalpable breast lesions who are to undergo open surgical biopsy has not been medically proven to be effective and is considered not medically necessary.

DESCRIPTION:

A percutaneous breast biopsy is performed by fine needle aspiration, needle core biopsy, vacuum assisted biopsy, or with a rotating device. Depending upon the abnormality to be biopsied ultrasonic, stereotactic, or MRI guidance to localize the abnormality may be required.

Stereotactic guidance is a radiological technique for localizing breast lesions. The technique requires that the breast be compressed between a compression paddle and a plate, called the image receptor, which can detect the x-ray beam and produce either a film image (mammogram) or a digital computer-generated image of the breast.

Devices approved by the FDA for percutaneous breast biopsy that utilize either a vacuum assisted or rotating device and image-guidance include, but are not limited to, the:

I. ABBI® (Advanced Breast Biopsy Instrumentation) System - a rotating device biopsy system that uses a circular scalpel and electrocautery snare to excise a large cylinder of tissue in route to and including the target area.

II. EnCor™ Breast Biopsy System – an open or closed vacuum assisted breast biopsy system that can be used with stereotactic, ultrasonic or MRI guidance.

III. ATEC® Breast Biopsy System - a closed vacuum assisted breast biopsy system that can be used with stereotactic, ultrasound, or MRI guidance and can collect up to 16 core biopsies per minute.

IV. Mammothome® System - a vacuum assisted biopsy system that uses suction to draw breast tissue into an opening in the side of a cylindrical probe. A rotating knife then cuts the tissue samples and removes them through the hollow chamber of the probe into a collection chamber.

V. SiteSelect® Breast Biopsy System - a rotating device biopsy system that uses a wire and disc blade to transect a tissue specimen removed from the targeted area only.

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VI. Vacora® Vacuum Assisted Biopsy System – a vacuum assisted breast biopsy system that can be used with stereotactic, ultrasonic or MRI guidance.

RATIONALE:

The ABBI®, ATEC®, EnCor™, Mammutome®, SiteSelect®, and Vacora® systems have received approval by the U.S. Food and Drug Administration (FDA) for diagnostic biopsy of breast abnormalities.

There are no studies directly comparing the diagnostic performance of vacuum assisted biopsy and conventional core biopsy, but the available data does suggest vacuum assisted biopsy results in an increased amount of tissue removed with a minimal complication rate. The technique has been thoroughly investigated in patients with nonpalpable lesions. However, there were no studies identified that focus on vacuum assisted biopsy with palpable lesions.

Positive conclusions as to the safety and efficacy of stereotactic guidance for percutaneous biopsies of nonpalpable breast lesions have been made. Stereotactic localization of nonpalpable breast lesions is being performed routinely throughout the United States. Evidence is inadequate to determine if stereotactic localization of palpable breast lesions provide adequate sampling of tissue for pathologic analysis.

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<thead>
<tr>
<th>CODES</th>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.</td>
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CPT:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>19081</td>
<td>Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance (effective 1/1/14)</td>
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<tr>
<td>19082</td>
<td>each additional lesion, including stereotactic guidance (effective 1/1/14)</td>
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<td>19083</td>
<td>Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance (effective 1/1/14)</td>
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<td>19084</td>
<td>each additional lesion, including ultrasound guidance (effective 1/1/14)</td>
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<td>19085</td>
<td>Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance (effective 1/1/14)</td>
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<td>19086</td>
<td>each additional lesion, including magnetic resonance guidance (effective 1/1/14)</td>
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<td>19102</td>
<td>Biopsy of breast; percutaneous, needle core, using imaging guidance</td>
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<td>19103</td>
<td>percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance</td>
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<td>19281</td>
<td>Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance (effective 1/1/14)</td>
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<td>19282</td>
<td>each additional lesion, including mammographic guidance (effective 1/1/14)</td>
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19283  Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance (effective 1/1/14)
19284  each additional lesion, including stereotactic guidance (effective 1/1/14)
19285  Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance (effective 1/1/14)
19286  each additional lesion, including ultrasound guidance (effective 1/1/14)
19287  Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance (effective 1/1/14)
19288  each additional lesion, including magnetic resonance guidance (effective 1/1/14)
19295  Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration
77031  Stereotactic localization guidance for breast biopsy or needle placement (eg, for wire localization or for injection), each lesion; radiological supervision and interpretation

**HCPCS:** No code(s)

**ICD9:**

174.0-174.9  Malignant neoplasm, female breast (code range)
175.0-175.9  Malignant neoplasm, male breast (code range)
217  Benign neoplasm of breast
233.0  Carcinoma in situ of breast
238.3  Neoplasm of uncertain behavior, breast
239.3  Neoplasm of unspecified nature, breast
793.8-793.9  Nonspecific abnormal findings on radiological and other examination, breast

**ICD10:**

C50.011-C50.929  Malignant neoplasm of the breast (code range)
D05.00-D05.92  Carcinoma in situ of the breast (code range)
D24.1-D24.9  Benign neoplasm of the breast (code range)
D48.60-D48.62  Neoplasm of uncertain behavior of the breast (code range)
D49.3  Neoplasm of unspecified behavior of the breast
R92.8  Other abnormal and inconclusive findings on diagnostic imaging of breast
R93.9  Diagnostic imaging inconclusive due to excess body fat of patient

**REFERENCES**

*Previously titled Stereotactic Breast Biopsy.*

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*United States Food and Drug Administration. The grey sheet. 1997 Jan 6;21(1).

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**KEY WORDS:**
ABBI®; ATEC®, Breast biopsy, percutaneous; Breast biopsy, stereotactic; Mammatome®, SiteSelect®, Vacuum-assisted breast biopsy.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a National Coverage Determination (NCD) regarding Percutaneous Image Guided Breast Biopsy. Please refer to the following website for Medicare Members:

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=272&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=Percutaneous+Image+Guided+Breast+Biopsy&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=220.13&ncd_version=1&basket=ncd%25253A220%25252E13%25253A1%25253APercutaneous+Image%25252DGuided+Breast+Biopsy&bc=gAAABAAAAA&