Overview Statement

The purpose of this Clinical Guideline is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to improve patient outcomes. This Clinical Guideline neither preempts clinical judgment of trained professionals nor advises anyone on how to practice medicine. The healthcare professionals are responsible for all clinical decisions based on their assessment. This Clinical Guideline is not an authorization, certification, explanation of benefits, or a guarantee of payment, nor does it substitute for, or constitute, medical advice.

Federal and State law, as well as member benefit contract language, including definitions and specific contract provisions/exclusions, take precedence over Clinical Guidelines and must be considered first when determining eligibility for coverage. All final determinations on coverage and payment are the responsibility of the health plan. Nothing contained within this document can be interpreted to mean otherwise.

Medical information is constantly evolving, and HealthHelp reserves the right to review and update this Clinical Guideline periodically.

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Ablation Services

The use of Ablation Services may be appropriate and supported by evidence to improve outcomes for patients who are being treated for various forms of cancer when the patient’s medical record demonstrates a clinical presentation supported by evidence based medicine (EBM).

Cryoablation:

**LIVER CANCER APPLICATION**

- Cryoablation utilization in the treatment of liver cancer may be reasonable and appropriate when the patient’s medical record demonstrates diagnosis of metastatic liver tumor which has been deemed un-resectable.

**PROSTATE CANCER APPLICATION**

- Cryoablation utilization in the treatment of prostate cancer may be reasonable and appropriate when the patient’s medical record demonstrates **EITHER** of the following:
  - Localized cancer, T1 or T2 and **ANY** of the following:
    - Cryobalation is being used as an alternative to surgery;
    - Cryoblation is being used as an alternative to radiation therapy;
    - Cryoablaton is NOT being used as alternative to surgery or radiation therapy, but rather as a post radiation therapy salvage therapy option.
  - Locally Advanced, T3 and **ANY** of the following:
    - Cryobalation is being used as an alternative to surgery;
    - Cryoblation is being used as an alternative to radiation therapy;
• Cryoablation is NOT being used as alternative to surgery or radiation therapy, but rather as a post radiation therapy salvage therapy option.

**RENA L/KIDNEY CANCER APPLICATION**

- Cryoablation utilization in the treatment of renal/kidney cancer may be reasonable and appropriate when the patient's medical record demonstrates diagnosis of renal cell carcinoma (RCC) and patient is not a candidate for a nephrectomy.

**ALL OTHER CANCER TYPES**

- All other cancer types not previously outlined will require review by the HealthHelp Medical Director for appropriateness as per current EBM.

**Microwave Ablation:**

**ALL CANCER TYPES**

- All requests for treatment of all cancer types with microwave ablation will require review by the HealthHelp Medical Director for appropriateness as per current EBM.

**Radiofrequency Ablation:**

**BONE CANCER APPLICATION**

- Radiofrequency Ablation (RFA) utilization in the treatment of bone cancer may be reasonable and appropriate when the patient's medical record demonstrates diagnosis of bone cancer and **ALL** of the following:
  - RFA is being used as an alternative to surgery;
  - Preserve function and/or prevent pathological fracture in a weight bearing bone;
o ECOG Performance Status is rated as a two (2) or less OR KPS is greater than or equal to 70.

**Renal/Kidney Cancer Application**

- Radiofrequency Ablation (RFA) utilization in the treatment of renal/kidney cancer may be reasonable and appropriate when the patient's medical record demonstrates diagnosis of RCC cancer and **ALL** of the following:
  o Not a surgical candidate;
  o Life expectancy of one (1) or more years;
  o ECOG Performance Status is rated as a two (2) or less OR KPS is greater than or equal to 70 and **ANY** of the following:
    - RCC tumor measures greater than 3cm with associated with intractable hematuria and localized this is for treatment of localized recurrence of RCC in a patient with a previous nephrectomy;
    - RCC tumor measures 3cm or smaller and **ANY** of the following:
      - Tumors are centrally located, near the hilum or collection system for treatment of localized recurrence of RCC in a patient with a previous nephrectomy;
      - Tumors are confined to the kidney with at most one site of metastasis;
      - Tumors are in the periphery of the kidney, away from the hilum and collection system.
Excisional Biopsy

Breast Biopsy

The use of Excisional Biopsy of the breast may be appropriate and supported by evidence to improve outcomes for patients who are being evaluated for primary breast cancer when the patient's medical record demonstrates the following:

1. Physician is not planning to perform a lumpectomy in conjunction with an excisional biopsy. The patient has had prior breast imaging performed via MRI/ultrasound of the breast or mammogram; and ANY of the following:
   - Patient does not have ANY of the following:
     - Breast abnormality that fluctuates with menstrual cycle;
     - Breast abnormality which is BI-RADS 1-3;
     - A cystic breast mass;
     - Suspected fibro adenoma of the breast;
     - Vascular malformation of the breast.
   - Patient has had a previous incisional biopsy with ANY of the following:
     - Discordance between imaging characteristics and core biopsy histology;
     - Core needle biopsy which was either non-diagnostic or highly suspicious of cancer;
     - Non-diagnostic specimen from core biopsy due to insufficient material, lack of calcifications or hemorrhage;
     - Suspicious interval changes are present in a lesion which was previously diagnosed benign by core biopsy;
     - Atypical hyperplasia (ductal or lobular) or lobular carcinoma in-situ (LCIS) present on core biopsy;
     - Papillary and/or sclerosing lesion on core biopsy;
- Fibro epithelial lesion (fibro adenoma vs benign phyllodes tumor) on core biopsy.
  - Patient has not had a previous biopsy with **ANY** of the following:
    - Patient has a cystic breast mass that does not resolve after one or more attempts at drainage;
    - Lesion is not anatomically suitable for core biopsy, i.e. lesion is too far anterior or posterior or is too close to a breast implant;
    - Patient is anatomically unsuitable for biopsy, i.e. breast tissue is too thin or patient is too large for the biopsy table;
    - Suspicious nipple discharge is present with normal breast imaging.
REFERENCES

Lumpectomy: Breast

The use of Lumpectomy of the breast may be appropriate and supported by evidence to improve outcomes for patients who are being treated for primary breast cancer when the patient’s medical record demonstrates the following:

1. Physician is not planning to perform an excisional biopsy in conjunction with the lumpectomy; and EITHER of the following:
   o Lumpectomy is being done for consideration of recurrence of previously known breast cancer in a patient who did not undergo neoadjuvant chemotherapy and who has had a core biopsy performed; and EITHER of the following:
     ☑️ Request is for a repeat lumpectomy; and EITHER of the following:
       • Repeat lumpectomy to the same site as the previous lumpectomy being performed for margin clearance;
       • Repeat lumpectomy to a different site than the previous lumpectomy.
     ☑️ Request is for an initial lumpectomy; and BOTH of the following:
       • Core biopsy was positive for malignancy;
       • Sentinel node biopsy is planned.
   o Lumpectomy is for initial diagnosis of breast cancer in a patient who has had a core biopsy performed, but has not undergone neoadjuvant chemotherapy; and EITHER of the following:
     ☑️ Request is for a repeat lumpectomy; and EITHER of the following:
       • Repeat lumpectomy to the same site as the previous lumpectomy being performed for margin clearance;
       • Repeat lumpectomy to a different site than the previous lumpectomy.
     ☑️ Request is for an initial lumpectomy; and BOTH of the following:
- Core biopsy was positive for malignancy;
- Sentinel node biopsy is planned.
REFERENCES

Mastectomy

Simple Mastectomy:

Simple Mastectomy may be medically appropriate and supported by evidence to improve patient outcomes for the following indications.

- Curative Mastectomy to treat current diagnosis of primary breast cancer.
- Prophylactic Mastectomy to decrease risk of bilateral breast cancer in patients who have tested positive for the BRCA-1 or BRCA-2 gene but who have not been diagnosed with breast cancer.
- Prophylactic Mastectomy to decrease risk of contralateral breast cancer in patients may be reasonable and appropriate when the patient’s medical record demonstrates the following:
  - Diagnosis of breast cancer; and ANY of the following:
    - Tested positive for either the BRCA-1 or BRCA-2 gene;
    - Patient has a first degree relative with breast cancer;
    - Patient has a history of radiation therapy to the chest wall.

Gynecomastia

Utilization of Mastectomy for the treatment of gynecomastia may be medically appropriate and supported by evidence to improve patient outcomes for the following indications.

- The utilization of mastectomy to treat gynecomastia may be considered reasonable and appropriate when the patient’s medical record demonstrates EITHER of the following:
Patient is diagnosed with Kleinfelter's Syndrome;

Patient is experiencing persistent pain or tenderness secondary to the breast tissue; and **ALL** of the following:

- Gynecomastia has been present for greater than twelve (12) months;
- There has been no regression of the condition despite treatment/withdrawal of causative factors for at least the past twelve (12) months;
- Pharmacological causes have been ruled out;
- Gynecomastia is classified as Grade II or greater.
REFERENCES

- Memorial Sloane Kettering Cancer Center. 2014. Breast Surgery Guidelines Take Aim at Unnecessary Operations
- BreastCancer.org. New Guidelines Say Lumpectomy Margins Can Be Small as Long as Tumor Has No Ink on It
- Cancermonthly.com. Study Concludes That Mammography Can Lead to Unnecessary Lumpectomies, Mastectomies and Radiation Therapy
Peripheral Revascularization

Utilization of peripheral revascularization for the treatment of peripheral vascular disease may be medically appropriate and supported by evidence to improve patient outcomes for the following indications.

Peripheral Angioplasty

- Peripheral Angioplasty for revascularization of the femoral/popliteal artery may be reasonable and appropriate when the patient's medical record demonstrates ANY of the following:
  - Symptoms of acute/chronic limb ischemia are present;
  - Symptoms of claudication are present and causing significant disability/inability to complete activities of daily living (ADL) and the patient has undergone structured physical therapy without relief;
  - Symptoms of peripheral vascular disease (PAD) are present on physical exam and there is a non-healing or gangrenous wound to the lower extremity, which has been evaluated and determined to be caused by PAD.

- Peripheral Angioplasty for revascularization of the tibial/peroneal artery may be reasonable and appropriate when the patient's medical record demonstrates ANY of the following:
  - Symptoms of acute/chronic limb ischemia are present;
  - Symptoms of claudication are present and causing significant disability/inability to complete activities of daily living (ADL) and the patient has undergone structured physical therapy without relief;
  - Symptoms of peripheral vascular disease (PAD) are present on physical exam and there is a non-healing or gangrenous wound to the lower extremity, which has been evaluated and determined to be caused by PAD.
- Peripheral Angioplasty for treatment of a popliteal or femoral aneurysm may be reasonable and appropriate when the patient’s medical record demonstrates **ANY** of the following:
  - Ultrasound imaging demonstrates a popliteal aneurysm measuring 2cm or greater;
  - Ultrasound imaging demonstrates a femoral aneurysm measuring 2cm or greater;
  - The patient has had an embolic event stemming from an aneurysm of the popliteal or femoral artery.

**Peripheral Atherectomy**

- Peripheral Atherectomy for revascularization of the femoral/popliteal artery may be reasonable and appropriate when the patient’s medical record demonstrates **ANY** of the following:
  - Symptoms of acute/chronic limb ischemia are present;
  - Symptoms of claudication are present and causing significant disability/inability to complete activities of daily living (ADL) and the patient has undergone structured physical therapy without relief;
  - Symptoms of peripheral vascular disease (PAD) are present on physical exam and there is a non-healing or gangrenous wound to the lower extremity, which has been evaluated and determined to be caused by PAD.

- Peripheral Atherectomy for revascularization of the tibial/peroneal artery may be reasonable and appropriate when the patient’s medical record demonstrates **ANY** of the following:
  - Symptoms of acute/chronic limb ischemia are present;
  - Symptoms of claudication are present and causing significant disability/inability to complete activities of daily living (ADL) and the patient has undergone structured physical therapy without relief;
Symptoms of peripheral vascular disease (PAD) are present on physical exam and there is a non-healing or gangrenous wound to the lower extremity, which has been evaluated and determined to be caused by PAD.

- Peripheral Atherectomy for treatment of a popliteal or femoral aneurysm may be reasonable and appropriate when the patient's medical record demonstrates ANY of the following:
  - Ultrasound imaging demonstrates a popliteal aneurysm measuring 2cm or greater;
  - Ultrasound imaging demonstrates a femoral aneurysm measuring 2cm or greater;
  - The patient has had an embolic event stemming from an aneurysm of the popliteal or femoral artery.

Peripheral Stenting

- Peripheral Stenting for revascularization of the femoral/popliteal artery may be reasonable and appropriate when the patient's medical record demonstrates ANY of the following:
  - Symptoms of acute/chronic limb ischemia are present;
  - Symptoms of claudication are present and causing significant disability/inability to complete activities of daily living (ADL) and the patient has undergone structured physical therapy without relief;
  - Symptoms of peripheral vascular disease (PAD) are present on physical exam and there is a non-healing or gangrenous wound to the lower extremity, which has been evaluated and determined to be caused by PAD.

- Peripheral Stenting for revascularization of the tibial/peroneal artery may be reasonable and appropriate when the patient's medical record demonstrates ANY of the following:
  - Symptoms of acute/chronic limb ischemia are present;
- Symptoms of claudication are present and causing significant disability/inability to complete activities of daily living (ADL) and the patient has undergone structured physical therapy without relief;
- Symptoms of peripheral vascular disease (PAD) are present on physical exam and there is a non-healing or gangrenous wound to the lower extremity, which has been evaluated and determined to be caused by PAD.

Peripheral Stenting for treatment of a popliteal or femoral aneurysm may be reasonable and appropriate when the patient's medical record demonstrates ANY of the following:

- Ultrasound imaging demonstrates a popliteal aneurysm measuring 2 cm or greater;
- Ultrasound imaging demonstrates a femoral aneurysm measuring 2 cm or greater;
- The patient has had an embolic event stemming from an aneurysm of the popliteal or femoral artery.
REFERENCES:

- Iso, Y, Suzuki, H. Exercise therapy for intermittent claudication in peripheral artery disease: An article form the e-journal of the ESC Council for Cardiology Practice. 2015; 13(34).
Thoracoscopy: Lung Wedge Resection

Performing a Thoracoscopy: Lung Wedge Resection may be medically appropriate and supported by evidence to improve patient outcomes for the purposes of diagnostic biopsy of lung infiltrates, nodules or in cases where an initial therapeutic wedge resection is required for the following indications.

1. Thoracoscopic lung wedge resection for Stage I or Stage II lung cancer may be reasonable and appropriate when the patient’s medical record demonstrates ALL of the following:
   - Patient has had a CT of the Chest and FDG-PET scans to evaluation all primary pulmonary lesions;
   - Primary lesion is located in the outer 1/3 of the affected lung field; and BOTH of the following:
     - Primary lesion measuring less than or equal to three (3) centimeters (cm) in diameter;
     - Primary lesion type is either non-solid or greater than 50% in ground glass appearance on CT of the Chest.
   - There is histological confirmation of primary lung cancer via biopsy; and ANY of the following:
     - Patient has a cardiovascular co-morbidity or high pre-operative cardiac risk; and BOTH of the following:
       - Patient has had a cardiopulmonary exercise test to assess surgical risk resulting in either low risk (VO2max>20ml/kg/min or >75%) or moderate risk (VO2max 10-20 ml/kg/min or 35-75%).
• Complete resection of the tumor in its entirety will be achieved with the primary malignancy controlled.

• Patient has no cardiovascular co-morbidity, sufficient pulmonary reserve as determined by pulmonary function testing (PFT) and complete resection of the tumor in its entirety will be achieved with the primary malignancy controlled.

• Patient has had PFT with predicted postoperative forced expiratory volume (PPO FEV₁) and diffusing capacity for carbon monoxide (DLCO) calculations performed; and BOTH of the following:
  • Patient has had a cardiopulmonary exercise test to assess surgical risk resulting in either low risk (VO₂max>20ml/kg/min or >75%) or moderate risk (VO₂max 10-20 ml/kg/min or 35-75%);
  • Complete resection of the tumor in its entirety will be achieved with the primary malignancy controlled.

2. Thoracoscopic lung wedge resection for pulmonary metastasis (metastasectomy) may be reasonable and appropriate when the patient’s medical record demonstrates ALL of the following:
   o Patient has had a CT of the Chest and FDG-PET scans to evaluation all primary pulmonary lesions;
   o Patient has one (1) to seven (7) pulmonary metastatic lesions found on imaging;
   o There is histological confirmation of pulmonary metastasis via biopsy; and ANY of the following:
     • Patient has a cardiovascular co-morbidity or high pre-operative cardiac risk; and BOTH of the following:
       • Patient has had a cardiopulmonary exercise test to assess surgical risk resulting in either low risk (VO₂max>20ml/kg/min or >75%) or moderate risk (VO₂max 10-20 ml/kg/min or 35-75%);
• Complete resection of the tumor in its entirety will be achieved with the primary malignancy controlled.

B Patient has no cardiovascular co-morbidity, sufficient pulmonary reserve as determined by pulmonary function testing (PFT) and complete resection of the tumor in its entirety will be achieved with the primary malignancy controlled.

B Patient has had PFT with predicted postoperative forced expiratory volume (PPO FEV1) and diffusing capacity for carbon monoxide (DLCO) calculations performed; and BOTH of the following:

• Patient has had a cardiopulmonary exercise test to assess surgical risk resulting in either low risk (VO2max>20ml/kg/min or >75%) or moderate risk (VO2max 10-20 ml/kg/min or 35-75%);

• Complete resection of the tumor in its entirety will be achieved with the primary malignancy controlled.

3. Thoracoscopic lung wedge resection may be reasonable and appropriate when the patient’s medical record demonstrates intervention required for recurrent spontaneous pneumothorax or diagnostic procedure for the evaluation of interstitial lung disease.
REFERENCES

The use of thyroidectomy may be appropriate and supported by evidence to improve outcomes for patients who are being evaluated for primary breast cancer when the patient's medical record demonstrates the following:

2. Thyroid lobectomy may be medically appropriate and supported by evidence to improve patient outcomes for the following indication:
   - Fine needle aspiration demonstrates follicular neoplasm (i.e. micro follicular, cellular or indeterminate type), and **EITHER** of the following:
     - TSH level of less than 1mU/mL;
     - TSH level of greater than or equal to 1mU/mL and molecular testing is not available.

3. Total thyroidectomy may be medically appropriate and supported by evidence to improve patient outcomes for the following indication:
   - Fine needle aspiration, surgical and/or histological specimen pathology demonstrates definitive thyroid cancer or metastatic cancer to the thyroid.

3. Any other indication for thyroidectomy will require escalated medical necessity review.
REFERENCES

## APPENDIX A: CPT AND HCPCS CODES ASSOCIATED WITH THIS POLICY

Any CPT or HCPCS codes that have been associated with this HealthHelp Clinical Guideline are for informational use only. The inclusion of a code in this guideline does not guarantee coverage or reimbursement by the individual health plan.

### ONCOLOGY SURGERY

#### Excisional Biopsy - Breast

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<thead>
<tr>
<th>Description</th>
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<tr>
<td>Excision of cyst, fibro adenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion (except 19300), open, male or female, 1 or more lesions</td>
<td>19120</td>
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<tr>
<td>Excision of breast lesion identified by preoperative placement of radiological marker, open; single lesion</td>
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#### Lumpectomy - Breast

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<td>Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy);</td>
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<tr>
<td>Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadentectomy</td>
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#### Mastectomy - Breast

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<td>Mastectomy for gynecomastia</td>
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<td>Mastectomy, simple, complete</td>
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<td>Mastectomy, subcutaneous</td>
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#### Biopsy / Wedge Resection - Lung

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<tr>
<td>Thoracotomy, with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral</td>
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<tr>
<td>Thoracotomy, with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral</td>
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<tr>
<td>Thoracotomy; with therapeutic wedge resection (eg, mass, nodule), initial</td>
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<td>Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral</td>
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<tr>
<td>Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral</td>
<td>32608</td>
</tr>
<tr>
<td>Thoracoscopy, surgical; with therapeutic wedge resection (eg, mass, nodule), initial unilateral</td>
<td>32666</td>
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