

I. BACKGROUND/RESEARCH

Overall, women in the U.S. have a 12.5% lifetime risk of developing breast cancer and a 3.5% lifetime risk of dying from the disease.¹ Certain women fall into high risk groups in which cancer incidence is markedly increased. A woman with a family history of breast cancer in first and second-degree relatives has a relative risk of 2 to 3. Women who carry the BRCA1 or BRCA2 gene have a lifetime risk of breast cancer estimated from 60-90%.² These women should receive genetic counseling that should include risk assessment and, as appropriate, genetic testing to assist them in considering these options.³ Other groups of women at high risk include those with atypical hyperplasia, diffuse microcalcification, fibrocystic breast disease, lobular carcinoma in situ (LCIS), and prior history of cancer of the opposite breast.

Women who fall into a high risk group for the development of breast cancer have a number of options available to manage their risk. Surveillance alone, with careful clinical follow-up, breast self-examination and appropriate regular imaging studies is one option. Unfortunately, the efficacy of mammography in reducing breast cancer mortality for women at increased risk, especially younger women, is not established. Likewise, the efficacy of breast examination alone in reducing mortality has not been demonstrated. A medical option that has shown promise in risk reduction is Tamoxifen.⁴ Tamoxifen has been shown to reduce the risk of invasive breast cancer by 49% and the risk of noninvasive cancer by 50%. Its effects may be limited to Estrogen Receptor Positive (ER+) tumors, and its effect in BRCA1 and BRCA2 carriers is unknown. Surgical options that have shown risk reduction effects include bilateral oophorectomy and bilateral risk-reduction mastectomy, which has traditionally been called prophylactic mastectomy (PM). Bilateral oophorectomy has shown a risk reduction of 50% in BRCA1 carriers.⁵ Bilateral prophylactic mastectomy carries a risk reduction of greater than 90% in high risk women with or without the BRCA1 or BRCA2 gene.^{6,7} Studies have shown significant psychological benefit as well, with decreased anxiety in those who choose this option.⁸

Subcutaneous mastectomy, nipple sparing total mastectomy (NSTM) which leaves the nipple-areolar complex, or simple mastectomy, with removal of the nipple areolar complex, may be chosen. However, while desirable for aesthetic reasons, data shows that this choice may not be prudent and may compromise risk reduction obtained from the surgery.⁹ This may be especially true in populations that carry the BRCA1 or BRCA2 gene.

Women at high risk for developing breast cancer should discuss management options with their physician. This discussion should take into account her relative risk, her personal assessment of potential risks and benefits of various treatments, and her psychological state.

This Practice Parameter addresses the procedure of prophylactic mastectomy. Following the prophylactic mastectomy, breast reconstruction by various methods may be indicated. Options for breast reconstruction are the same in prophylactic mastectomy as they are for mastectomy for established malignant disease and will not be addressed in this Practice Parameter. Please see the related clinical practice guideline on breast reconstruction for information on that procedure.

The Women's Health and Cancer Rights Act of 1998 requires that insurers provide health insurance coverage in connection with a group health plan that provides medical and surgical benefits for mastectomy, provide, in a case of a participant who is receiving benefits in connection with a mastectomy and who elects breast reconstruction, coverage for reconstruction of the breast, surgery of the other breast to produce a symmetrical appearance, prostheses, and complications. It is the position of the ASPS that prophylactic coverage should be covered under this federal mandate, however, government regulations have not been finalized.

II. DIAGNOSTIC CRITERIA

A woman may present for bilateral prophylactic mastectomy with no prior personal history of breast cancer. In such cases, the woman may have a biopsy showing atypical hyperplasia or carry a family history that is positive for breast cancer. Family patterns that would be considered positive for breast cancer include:

1. Two or more first-degree relatives
2. One first-degree and 2 second or third-degree relatives
3. One first-degree relative with cancer prior to age 45 and one other relative
4. One first-degree relative and one first-degree relative w/ovarian CA
5. Two second or third-degree relatives and one relative w/ovarian CA
6. Three or more second or third-degree relatives
7. One first-degree relative with bilateral cancer
8. Positive BRCA1 or BRCA2

Women also seek prophylactic mastectomy for the opposite breast after having had breast cancer. They may want this surgery for various reasons, including the fact that mammography findings may demonstrate diffuse microcalcifications, fibrocystic breast disease, lobular carcinoma in situ, or invasive lobular cancer. In addition, in patients who have had cancer of the opposite breast at an early age (< 40 years), their lifetime risk of occurrence in the opposite breast is increased. Also, women who have had cancer in one breast and whose remaining breast is large and/or difficult to examine may benefit from prophylactic mastectomy. Thus, a combination of physical and psychological factors can influence a woman's decision to have prophylactic mastectomy.⁷

III. TREATMENT

PREOPERATIVE

Candidates for prophylactic mastectomy should be evaluated in terms of general health and psychological fitness. The physical should include examination of breasts for signs suggestive of cancer. If the patient has had previous mastectomy, that site should be examined for signs suggestive of recurrence. That site should also be examined for potential reconstructive procedures, if this has not already been done. Additionally, if a personal history of cancer exists, the patient should be examined for potential metastatic sites (e.g. lymphatic, pulmonary, neurologic, osseous).

Appropriate laboratory studies and radiologic evaluation would include:

1. Appropriate preoperative bloodwork (e.g. CBC and liver profile)
2. Genetic testing, if desired and indicated
3. Chest x-ray, if indicated
4. Mammography or other breast imaging, if indicated
5. MRI or CT scanning for suspected metastasis

Consultations with other medical specialists may be indicated:

- Oncologic consultation for risk assessment, medical management
- Psychiatrist/psychologist for evaluation of anxiety/depression
- Internist for medical management
- Gynecologist for assessment for bilateral oophorectomy

If the patient is found not to be a candidate for surgery, either through her own choice or upon physician recommendation, non-operative management of the opposite breast should include continued surveillance and chemoprophylaxis, if indicated. The patient may also elect to wear an external prosthesis for symmetry.

OPERATIVE

Treatment options include:

Simple mastectomy (total mastectomy). In this procedure, breast skin flaps are developed and the breast removed in the same fashion as for modified radical mastectomy. Care should be taken to remove the axillary tail, perhaps with one or more lower axillary nodes, but a node dissection is not done. The nipple areolar complex is removed, although a skin sparing type of procedure can be performed. If reconstruction is not done, more skin will usually need to be removed to produce a satisfactory aesthetic result.

Nipple sparing mastectomy (NSTM). This procedure differs from simple mastectomy only in that the nipple areolar complex is left in place. Incisions around the areola, lateral to the areola, and the inframammary crease have been described. Carving of the nipple can be done to remove as much of the ductal elements as possible. Removal of the breast compromises the blood supply of the skin flaps, and flap necrosis can occur. The advisability of using hyperbaric oxygen has been suggested.

With either method of prophylactic mastectomy, reconstruction of the breast mound and/or the nipple areolar complex may be elected. As with breast reconstruction after modified radical mastectomy, procedures fall into two basic categories: implants and autologous tissue. Both methods often require more than one stage for completion.

The decision to have breast reconstruction, either immediate or delayed, is a highly personal decision. Many factors can influence the woman's decision including age, marital status, children, concerns about body image, and psychological distress.¹⁰ Various surgical techniques can be used for the reconstruction including implants or the use of autologous tissue. Autologous tissue techniques include latissimus dorsi flaps, with or without implants, TRAM or free flaps. Research supports a high degree of patient satisfaction with prophylactic mastectomy and breast reconstruction, as well as a decrease in breast cancer risk.^{11,12}

POSTOPERATIVE

Prophylactic mastectomy can be performed on either an inpatient or outpatient basis. For the woman who elects to have surgery as an outpatient, it is essential that there be adequate home care following surgery. If reconstruction is performed, hospitalization may be indicated. The length of stay is dictated by the specific reconstructive procedure. In the first few postoperative days, wound assessment and pain management will be most important. All patients will need to visit the physician's office periodically for wound assessment, drain removal and suture removal during the first several weeks. Postoperative visits may continue for up to a year.

Initially, the wound must be assessed daily. If drains are used, they must be managed daily until they are removed. The wound must also be observed for signs of infection and other possible complications as follows: hemorrhage, hematoma, seroma, skin necrosis, nipple/areola necrosis, unfavorable scarring, unfavorable aesthetic result, failure to prevent breast cancer, and asymmetry. It may be necessary to surgically revise the site for any of these complications.

PROVIDER QUALIFICATIONS

The individual performing this procedure, regardless of the location of the surgical facility, should have fully approved hospital privileges for this procedure and be qualified for examination or be certified by a surgical board recognized by the American Board of Medical Specialties®, such as The American Board of Plastic Surgery®.

IV. DISCLAIMER

Patient Care Parameters are strategies for patient management developed to assist physicians in clinical decision-making. This Patient Care Parameter, based on a thorough evaluation of scientific literature and relevant clinical experience, describes a range of generally acceptable approaches to diagnose, manage or prevent specific diseases or conditions. This Patient Care Parameter attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.



However, this Patient Care Parameter should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgement regarding the care of a particular patient must be made by the physician in light of all the circumstances presented by the patient, the diagnostic and treatment options available, and available resources.

This Patient Care Parameter is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. This Patient Care Parameter reflects the state of knowledge current at the time of publication. Given the inevitable changes in the state of scientific information and technology, periodic review, updating and revision will be done.

V. CODING

The following codes are provided as a guideline for the physician and are not meant to be exclusive of other possible codes. Other codes may be acceptable depending on the nature of any given procedure.

Diagnosis	ICD-9
Family history of malignant neoplasm of breast	V16.3
Personal history of malignant neoplasm of breast	V10.3
Fibrocystic breast disease	610.1
Malignant neoplasm of female breast	174.0-174.9
Malignant neoplasm of male breast	175.0-175.9
Carcinoma in situ of the breast	233.0
Neoplasm of uncertain behavior of the breast	238.3

Procedure	CPT Code
Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)	19301
with axillary lymphadenectomy	19302
Mastectomy, simple, complete	19303
Mastectomy, subcutaneous	19304
Mastectomy, radical, including pectoral muscles, axillary lymph nodes	19305

Procedure

Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation)

CPT Code

19306

Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle

19307

VI. REFERENCES

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Approved by the ASPS® Executive Committee: March 2003, Coding Updated May 2008.

