Clinical Rationale

- The American Cancer Society estimate of new cases of breast cancer in the United States in 2005 includes 212,930 new cases of breast cancer and 40,870 deaths from the disease.[1]
- Tamoxifen was approved by the Food and Drug Administration in 1977 for the treatment of women with advanced breast cancer, and later for the adjuvant treatment of primary breast cancer [2] and for the reduction of breast cancer risk in those at increased risk for the disease.[3]
- A 1998-99 survey found that tamoxifen was used in 55.8% of patients treated for breast cancer that year.[4]

Reason for Indicated Intervention or Treatment

- For asymptomatic women taking tamoxifen, several studies have demonstrated that endometrial cancer screening measures with routine transvaginal ultrasonography, endometrial biopsy, or both are not effective, and may be counterproductive due to the invasiveness of the procedures.[5-9] One retrospective study, however, suggests that transvaginal ultrasound with diagnostic hysteroscopy reliably evaluates endometrial polyps, however, this type of screening may not be cost effective.[10]
- No studies examining the efficacy of gynecological examinations in patients taking tamoxifen have been conducted.

Evidence supporting Intervention or Treatment

- A 2005 meta-analysis by the Early Breast Cancer Trialists' Collaborative Group of 37,000 women in 55 randomized, controlled trials found that patients treated with tamoxifen had a highly statistically significant increase in the incidence of endometrial cancer (ratio of incidence rates 2.58, standard deviation 0.35).[11]
- Another meta-analysis of 23 randomized, controlled trials with 45,936 patients also showed that tamoxifen was significantly associated with an increased risk of endometrial cancer (relative risk (RR) 2.70, 95% CI, 1.94 to 3.75).[12]
- One randomized, controlled trial in 2005 demonstrated that both pre and post-menopausal women on tamoxifen had a greater incidence of endometrial polyps, leiomyomas, endometriosis, ovarian cysts (pre-menopausal only), and gynecological surgical procedures, including...
hysterectomy.\[13\]

- The rate of complications (including endometrial disease) increases with the number of years that a woman takes tamoxifen.\[14, 15\] The optimum dosage length is controversial, however, trials have suggested that five years may be the optimal length of time.\[16, 17\]

### Clinical Recommendations

- The American College of Obstetricians and Gynecologists' Committee on Gynecological Practice recommends close monitoring for symptoms of endometrial hyperplasia in women taking tamoxifen, and suggests that these patients get at least one gynecologic examination per year.\[18\]
- One Italian guideline suggests that endometrial assessment, before the start of tamoxifen treatment is recommended for all menopausal patients with receptor positive breast cancer.\[19\]

### Source

Health Benchmarks, Inc.

### Denominator

Continuously enrolled women who had at least 180 days supply of Tamoxifen during the year prior to the measurement year.

### Denominator Exclusion

Women who have had a hysterectomy at anytime prior to the end of the measurement year.

### Relevant billing Codes:

**ICD-9 surgical procedure codes:** 68.5x, 68.3x, 68.4x, 68.6x, 68.7x, 68.8x, 68.9x

**CPT-4 codes:** 01962, 01963, 01969, 45126, 51597, 51925, 56308, 58150, 58152, 58180, 58200, 58210, 58240, 58260-58270, 58275, 58280, 58285, 58290, 58291, 58292, 58293, 58294, 58550, 58552, 58553, 58554, 58951, 58953, 58954, 58956, 59135, 59525

### Numerator

Women who received at least one gynecological evaluation, pelvic exam, or endometrial biopsy within the 365 days after the index prescription date, exclusive of the index date. Women with a claim for a gynecological exam or with a physician-administered pap test will also be counted toward the numerator.

### Relevant billing Codes:

**ICD-9-CM DX codes in any diagnosis field:** 795.0x, 795.1x

**ICD-9 CM V-status codes:** V72.3x, V72.32

**ICD-9 surgical procedure codes:** 91.46

**CPT-4 codes:** 58100, 58110, 88141-88145, 88147, 88148, 88150, 88152-88155, 88164-88167, 88174-88175

**HCPCS codes (in CPT-4 field):** G0101, G0123, G0124, G0141, G0143, G0144, G0145, G0147, G0148, P3000, P3001, Q0060, Q0061, Q0063, Q0091

**UB-92 Revenue codes:** 0923, 923
Interpretation of Score
High score implies better performance

Physician Attribution
Score all physicians (in the selected specialties) who saw the member 365 days after the index prescription date.

References


Indicator Classification (Adapted from Health Plan Employer Data Information Set (HEDIS®) technical specifications)

**Diagnosis**
Measures applicable to patients receiving diagnostic workups for a symptom or condition that delineate appropriate laboratory or radiological testing to be performed (e.g. evaluation of thyroid nodule; pregnancy test in patients with vaginal bleeding or abdominal pain).

**Effectiveness of Care**

**Prevention**
Measures applicable to asymptomatic individuals that are designed to prevent the onset of the targeted condition (e.g. immunizations).

**Screening**
Measures applicable to asymptomatic patients who have risk factors or preclinical disease, but in whom the condition has not become clinically apparent (e.g. pap smears; screening for elevated blood pressure).

**Disease Management**
Measures applicable to individuals diagnosed with a condition that are part of the treatment or management of the condition (e.g. cholesterol reduction in patients with diabetes; radiation therapy following breast conserving surgery; appropriate follow-up after acute event).

**Medication Monitoring**
Measures applicable to patients taking medications with narrow therapeutic windows and/or potential preventable significant side effects or adverse reactions (e.g. thyroid stimulating hormone (TSH) testing after levothyroxine dose change; hepatic enzyme monitoring for patients using antifungal pharmacotherapy).

**Medication Adherence**
Measures applicable to patients taking medications for chronic conditions that are designed to assess patient adherence to medication (e.g. adherence to lipid lowering medication).

**Utilization**
Measures applicable to patients receiving treatment for a symptom or condition that advocate appropriate utilization of laboratory and pharmaceutical resources (e.g. conservative use of imaging for low back pain; inappropriate use of antibiotics for viral upper respiratory infection).
2 Strength of Recommendation

Strength of Recommendation Based on a Body of Evidence

- Is this a key recommendation for clinicians regarding diagnosis or treatment that merits a label? No → Strength of Recommendation not needed
  - Yes
    - Is the recommendation based on patient-oriented evidence (i.e., an improvement in morbidity, mortality, symptoms, quality of life, or cost)? No → Strength of Recommendation = C
      - Yes
        - Is the recommendation based on opinion, bench research, a consensus guideline, usual practice, clinical experience, or a case series study? No
          - Yes
            - Is the recommendation based on one of the following?
              - Cochrane Review with a clear recommendation
              - USPSTF Grade A recommendation
              - Clinical Evidence rating of Beneficial
              - Consistent findings from at least two good-quality randomized controlled trials or a systematic review/meta-analysis of same
              - Validated clinical decision rule in a relevant population
              - Consistent findings from at least two good-quality diagnostic cohort studies or systematic review/meta-analysis of same

**FIGURE 2.** Algorithm for determining the strength of a recommendation based on a body of evidence (applies to clinical recommendations regarding diagnosis, treatment, prevention, or screening). While this algorithm provides a general guideline, authors and editors may adjust the strength of recommendation based on the benefits, harms, and costs of the intervention being recommended. (USPSTF = U.S. Preventive Services Task Force)