Raloxifene and Tamoxifen for Risk Reduction of Primary Breast Cancer in Women

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The United States Preventative Services Task Force (USPSTF) has recommended clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer and those medications that reduce risk. Clinicians should consider prescribing risk-reducing medications such as tamoxifen or raloxifene if women are at an increased risk of breast cancer and at low risk for adverse medication effects.

The USPSTF recommends against the routine use of medications, such as tamoxifen or raloxifene, for risk reduction of primary breast cancer in women who are not at increased risk for breast cancer. The intent of this policy is to provide a way to identify female patients who are using the FDA approved medications: tamoxifen, in women 35 years of age and older, and raloxifene, in postmenopausal women for risk reduction of primary breast cancer. These identified members are eligible to receive cost share waiver for up to 5 years.

POLICY

I. **Tamoxifen** is **eligible for member cost share waiver** when used for risk reduction of primary breast cancer in females 35 years of age and older

   **Approval is lifetime, with cost share waiver applied for a maximum of 5 years.** If the medication is continued for more than 5 years, the member’s cost share will no longer be waived.

II. **Raloxifene** is **eligible for member cost share waiver** when used for risk reduction of primary breast cancer in postmenopausal females

   **Approval is lifetime, with cost share waiver applied for a maximum of 5 years.** If the medication is continued for more than 5 years, the member’s cost share will no longer be waived.

III. Tamoxifen and raloxifene are approved for other uses outside of this criteria, and as such, will be considered medically necessary, however, member cost share will not be waived. A lifetime approval will be given when a member does not meet the above stated criteria.
Breast cancer is the most common cancer in women in the United States with no regard to race or ethnicity, not counting some forms of skin cancer. It is the most common cause of death in Hispanic women. 232,340 new cases of breast cancer were expected to be diagnosed in 2013 as well as 39,620 deaths due to the disease. Screening allows for earlier detection of the disease but it does not prevent the occurrence. The United States Preventative Services Task Force (USPSTF) recommends that clinicians should consider prescribing risk-reducing medications such as tamoxifen or raloxifene if women are at an increased risk of breast cancer and at low risk for adverse medication effects. This recommendation applies to women who are 35 years and older without a previous diagnosis of breast cancer, ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS). These drugs should not be used in women who have an increased risk of thromboembolic events.

High risk is defined as women at least 35 years of age with a 5-year predicted risk of breast cancer greater than or equal to 1.67%, as calculated by the Gail Model. There are currently three models commonly used by health professionals. The Gail Model is considered to have limitations as it does not count on an in-depth family history. The Tyrer-Cuzik and Claus models are risk tools that are also used that are based largely on family history. All these tools are designed for health professionals to give a rough estimation of risk. Risk results may vary depending upon which tool is used. These tools cannot positively predict who will develop breast cancer.

There are several important risk factors for breast cancer. Unchangeable risks are age, race/ethnicity, age at menarche, age at first live childbirth, personal history of ductal or lobular carcinoma in situ, number of first-degree relatives with breast cancer, personal history of breast biopsy, menopause status or age and breast density. Modifiable risk factors include body mass index, estrogen and progestin use, smoking, alcohol use, physical activity and diet.

In a summary of primary prevention trials, tamoxifen and raloxifene versus placebo (6 independent trials), were found to reduce the incidence of invasive breast cancer by 7 (4-12, 95% CI and by 9 (4-14, 95% CI) per 1000 women over 5 years respectively. In STAR (Study of Tamoxifen and Raloxifene), a head-to-head trial, there were 5 (1-9, 95% CI) fewer events of invasive breast cancer per 1000 women using tamoxifen versus raloxifene. Both drugs when compared to placebo had 8 fewer events per 1000 women in regard to estrogen receptor-negative breast cancer (tamoxifen 8 (3-13, CI 95%) and raloxifene 8 (4-12, CI 95%).

In summary, tamoxifen and raloxifene, selective estrogen receptor modulators (SERMs) have been shown to reduce the incidence of invasive breast cancer in women who are at increased risk of the disease. Tamoxifen is approved for this use in women age 35 years and older at a usual daily dose of 20 mg daily for 5 years. Raloxifene has been approved for this use in postmenopausal women at a usual dose of 60 mg daily for 5 years.


POLICY HISTORY

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