

# DRUG DETERMINATION POLICY

**Title:** DDP-13 Breast Cancer Prevention

**Effective Date:** 06/01/2021



Physicians Health Plan  
PHP Insurance Company  
PHP Service Company

## Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

### 1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

### 2.0 Background or Purpose:

Medications for risk reduction of primary breast cancer are specialty drugs covered through the outpatient prescription drug benefit in compliance with the ACA. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

### 3.0 Clinical Determination Guidelines:

Document the Following with Chart Notes

#### A. General guidelines [must meet all listed below]:

1. Gender and age: women at least 35 years of age.
2. Indication: primary prevention of invasive breast cancer because the patient is deemed at high risk.
3. Disease status: no prior history of a diagnosis of breast cancer, ductal carcinoma in situ (DCIS) or lobular carcinoma (LCIS).
4. Drugs: tamoxifen, raloxifene.

#### B. Risk assessment:

1. Risk Assessment Tool: <http://www.cancer.gov/bcrisktool/> (see Appendix I).

2. Five-year high risk for breast cancer: at least 3% (United States Preventive Services Task Force (USPSTF) assessment for women at least 50 years of age).

C. Coverage at pre-deductible, no member cost share if criteria A and B above are met:

1. Approval and re-approval duration: one year.
2. Tamoxifen: liquid formulation only if cannot swallow or has difficulty swallowing tamoxifen tablets.
3. Raloxifene: all dose formulations.

**4.0 Coding:**

None.

**5.0 References, Citations & Resources:**

1. ESI Health Care Reform June 2014. PPACA Preventative Items & Services: Medications for Risk Reduction of Primary Breast Cancer.
2. National Cancer Institute: Breast Cancer Risk Assessment Tool <http://www.cancer.gov/bcrisktool/>
3. Tamoxifen, Soltamox *Drug Facts and Comparisons*. [database online] Wolters Kluwer Health Inc; 2014.
4. Evista *Drug Facts and Comparisons*. [Database online] Wolters Kluwer Health Inc; 2014.

**6.0 Appendices:**

See pages 3-4.

**7.0 Revision History:**

Original Effective Date: 10/23/2014

Next Review Date: 03/24/2022

Revision Date	Reason for Revision
4/19	Move to new format
3/20	Annual review; replaced abbreviations, indicated just generic medications are covered
2/21	Annual review, updated criteria instruction language; approved at 4/28/21 P&T

Appendix I: Estimating Risk of breast cancer (check the answer to the following questions)

1. Does the woman have a medical history of any breast cancer (CA) or of ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) or has she received previous radiation therapy to the chest for treatment of Hodgkin Lymphoma?

Yes  No

2. Does the woman have a mutation in either the *BRCA1* or *BRCA2* gene, or a diagnosis of a genetic syndrome that may be associated with elevated risk of breast cancer?

Unknown  Yes  No

3. What is the woman's age? ( $\geq 35$  years)

\_\_\_\_\_ Years

4. What was the woman's age at the time of her first menstrual period? (in years)

Unknown  7-11  12-13   $\geq 14$

5. What was the woman's age at the time of her first live birth of a child?

Unknown  No births   $<20$   20-24  25-29   $\geq 30$

6. How many of the woman's 1<sup>st</sup>-degree relatives (mother/sisters/daughters), have had breast CA?

Unknown  0  1   $>1$

7. Has the woman ever had a breast biopsy?

Unknown  No  Yes

a. How many breast biopsies (positive or negative) has the woman had?

1   $>1$

b. Has the woman had at least one breast biopsy with atypical hyperplasia?

Unknown  No  Yes

8. What is the woman's race/ethnicity?

White  African American  Hispanic  Asian-American

American Indian/Alaskan Native  Unknown

a. What is the sub race/ethnicity of the Asian-American?

Chinese  Japanese  Filipino  Hawaiian

Other Pacific Islander  Other Asian-American

Appendix II: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring/Contraindications	REMS
Evista raloxifene	<ul style="list-style-type: none"> <li>• Cardiovascular: hot flashes (10-25%)</li> <li>• Miscellaneous: weight gain (9%), flu syndrome (14-15%)</li> <li>• Pregnancy Category: X</li> </ul>	<ul style="list-style-type: none"> <li>• Labs: triglycerides with hypertriglyceridemia</li> <li>• Breast exam/mammogram pre and during</li> <li>• Contraindication: active/history of deep vein thrombosis (DTV), pregnancy, lactation</li> </ul>	<ul style="list-style-type: none"> <li>• None needed</li> </ul>
Tamoxifen tabs or liquid	<ul style="list-style-type: none"> <li>• Cardiovascular: hot flashes (80%),</li> <li>• Genitourinary: vaginal discharge (55%), vaginal bleeding (23%)</li> <li>• Pregnancy Category: D</li> </ul>	<ul style="list-style-type: none"> <li>• Labs: periodic CBC, liver function test, Triglycerides/cholesterol</li> <li>• Gynecological and breast exam/mammogram pre and during</li> <li>• Contraindication: active/history of DTV, on Coumadin</li> </ul>	<ul style="list-style-type: none"> <li>• None needed</li> </ul>