DRUG DETERMINATION POLICY

Title: DDP-13 Breast Cancer Prevention

Effective Date: 05/04/2022

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: 03/24/2023

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
02/23/2022	Annual, review, formatting

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? (≥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 ___ ≥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 ___ ≥30

6. How many of the woman's 1st-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	• Cardiovascular: hot flashes (10-25%) • Miscellaneous: weight gain (9%), flu syndrome (14-15%) • Pregnancy Category: X	• Labs: triglycerides with hypertriglyceridemia • Breast exam/mammogram pre and during • Contraindication: active/history of deep vein thrombosis (DTV), pregnancy, lactation	• None needed
Tamoxifen tabs or liquid	• Cardiovascular: hot flashes (80%), • Genitourinary: vaginal discharge (55%), vaginal bleeding (23%) • Pregnancy Category: D	• Labs: periodic CBC, liver function test, Triglycerides/cholesterol • Gynecological and breast exam/mammogram pre and during • Contraindication: active/history of DTV, on Coumadin	• None needed