

Pharmacy Benefit Determination Policy

Policy Subject: Breast Cancer Prevention Policy Number: SHS PBD39 Category: Child & Maternal Medicine Policy Type: <input type="checkbox"/> Medical <input checked="" type="checkbox"/> Pharmacy Department: Pharmacy	Dates: Effective Date: October 23, 2014 Revision Date: Approval Date: April 25, 2018 Next Review Date: April 2019
Product (check all that apply): <input checked="" type="checkbox"/> Group HMO/POS <input checked="" type="checkbox"/> Individual HMO/POS <input checked="" type="checkbox"/> PPO <input checked="" type="checkbox"/> ASO	Clinical Approval By: Medical Directors Peter Graham, MD Pharmacy and Therapeutics Committee Peter Graham, MD

Policy Statement: Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover medications for risk reduction of primary breast cancer without member cost share through the Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines
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Drugs and Applicable Coding: NA

Clinical Determination Guidelines: Document the Following with Chart Notes <ul style="list-style-type: none"> A. General Guidelines <ul style="list-style-type: none"> 1. Gender/Age: Women; \geq 35 years 2. Indication: Primary prevention of invasive breast Ca because the pt is deemed at high risk 3. Disease status: No prior history of a diagnosis of breast cancer (Ca), ductal carcinoma in situ (DCIS) or lobular carcinoma (LCIS) 4. Drugs: tamoxifen, Soltamox (liquid tamoxifen), Evista (raloxifene po) B. Risk Assessment: <ul style="list-style-type: none"> 1. Risk Assessment Tool: http://www.cancer.gov/bcrisktool/ (Appendix I) 2. 5-year high risk for breast Ca: \geq 3% (USPSTF assessment for women \geq 50 yrs old) C. Approval of no co-pay <ul style="list-style-type: none"> 1. Duration: 1 year 2. Soltamox (liquid tamoxifen): Cannot swallow or has difficulty swallowing tamoxifen tablets 3. Evista (raloxifene po): Women are post-menopausal
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Pharmacy Benefit Determination Policy

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**

Pharmacy Benefit Determination Policy

Appendix II: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring/Contraindications	REMS
Evista raloxifene	<ul style="list-style-type: none"> CV: Hot flashes (10-25%) Misc.: Weight gain (9%), flu syndrome (14-15%) Pregnancy: Category X 	<ul style="list-style-type: none"> Labs: triglycerides w hypertriglyceridemia Breast exam /mammogram pre & during Contraindication: Active/hx of DTV, Pregnancy, lactation 	<ul style="list-style-type: none"> None needed
Soltamox Tamoxifen liquid Tamoxifen tabs	<ul style="list-style-type: none"> CV: Hot flashes (80%), GU: Vaginal discharge (55%), vaginal bleeding (23%) Pregnancy: Category D 	<ul style="list-style-type: none"> Labs: Periodic CBC, LTF, Triglycerides/cholesterol Gynecological & breast exam /mammogram pre & during Contraindication: Active/hx of DTV, on coumadin 	<ul style="list-style-type: none"> None needed

References and 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.

Approved By:



4/25/18

Peter Graham, MD – PHP Executive Medical Director

Date

4/25/18

Human Resources (Kurt Batteen)

Date