

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

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| Program Number    | 2023 P 1138-12   |
| Program           | Prior Authorization/Regulatory   |
| Medication        | Breast Cancer Prevention Zero Dollar Cost Share - generic tamoxifen (applies to 20 mg dose only), generic raloxifene, generic aromatase inhibitors (anastrozole, letrozole, or exemestane) |
| P&T Approval Date | 7/2014, 8/2014, 5/2015, 8/2015, 7/2016, 7/2017, 4/2018, 6/2019, 12/2019, 7/2020, 8/2021, 1/2023  |
| Effective Date    | 4/1/2023;<br>Oxford only: 4/1/2023   |

**1. Background:**

The U.S. Preventive Services Task Force (USPSTF)<sup>1</sup> recommends that clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. For women who are at increased risk of breast cancer and at low risk of adverse medication effects, clinicians should offer to prescribe risk-reducing medications.

This program is designed to meet Health Care Reform requirements which require coverage of tamoxifen tablets, raloxifene or aromatase inhibitors [anastrozole (generic Arimidex), letrozole (generic Femara), or exemestane (generic Aromasin)] at zero-dollar cost share if being used for primary prevention of breast cancer and criteria are met.

**2. Coverage Criteria:**

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| <p><b>A.</b> Coverage at zero-dollar cost share will be approved based on <b>all</b> of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Member is greater than or equal to 35 years of age<sup>a</sup></li> </ol> <p style="text-align: center;"><b>-AND-</b></p> <ol style="list-style-type: none"> <li>2. Member does not have a prior diagnosis of <b>any</b> of the following:           <ol style="list-style-type: none"> <li>a. breast cancer</li> <li>b. ductal carcinoma in situ (DCIS)</li> <li>c. lobular carcinoma in situ (LCIS)</li> </ol> </li> </ol> <p style="text-align: center;"><b>-AND-</b></p> <ol style="list-style-type: none"> <li>3. Member does not have a history of thromboembolic events (e.g. deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)</li> </ol> <p style="text-align: center;"><b>-AND-</b></p> <ol style="list-style-type: none"> <li>4. Member has an estimated 5-year risk of breast cancer based on a breast cancer risk assessment tool of greater than or equal to 3%. <sup>2</sup></li> </ol> |
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-AND-

5. **One** of the following:

a. Request is for generic tamoxifen 20mg once daily

-OR-

b. Both of the following:

i. Member is post-menopausal

-AND-

ii. **One** of the following:

- (1) Request is for generic raloxifene 60 mg once daily
- (2) Request is for generic anastrozole
- (3) Request is for generic letrozole
- (4) Request is for generic exemestane, and member has had failure, contraindication or adverse reaction to anastrozole or letrozole

**Authorization will be issued for zero copay with deductible bypass for up to a total of 60 months (please determine if member has already received some length of therapy and if so subtract from total approval period).**

\* Typically excluded from coverage for the majority of business

<sup>a</sup> Not applicable to plans situated in District of Columbia

### 3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

### 4. **References:**

1. U.S. Preventive Services Task Force <http://www.uspreventiveservicestaskforce.org/> Accessed 12/2022
2. Assessment of Breast Cancer Risk Status. U.S. Preventive Services Task Force <https://bcrisktool.cancer.gov/> Accessed 12/2022

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|-----------------------|---|
| Program               | Prior Authorization/Regulatory - Breast Cancer Prevention Zero Dollar Cost Share - Tamoxifen (applies to 20 mg dose only), raloxifene       |
| <b>Change Control</b> |   |
| Date                  | Change  |
| 7/2014                | New program.  |
| 8/2014                | Added criteria for Evista requiring raloxifene as first line agent  |
| 5/2015                | Updated references.   |
| 8/2015                | Removed criterion requiring patient to be female per HCR requirements   |
| 7/2016                | Annual review. Minor revisions to background section.   |
| 7/2017                | Annual review. Administrative updates. Updated references.  |
| 4/2018                | Update for District of Columbia regulatory requirements.  |
| 6/2019                | Annual review. Updated references and additional clinical rules.  |
| 12/2019               | Removed brand Evista and Soltomox from criteria. Medications have been removed from first line Non Healthcare Reform Preventive Medication. |
| 7/2020                | Added coverage of Aromatase Inhibitors as in scope.   |
| 8/2021                | Annual review. Updated references.  |
| 1/2023                | Updated references.   |