UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 1138-8
Program	Prior Authorization/Regulatory
Medication	Breast Cancer Prevention Zero Dollar Cost Share - tamoxifen (applies to 20 mg dose only), Soltamox* (tamoxifen) solution, Evista (raloxifene)
P&T Approval Date	7/2014, 8/2014, 5/2015, 8/2015, 7/2016, 7/2017, 4/2018, 6/2019
Effective Date	9/1/2019; Oxford only: 9/1/2019

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1. Background:

The U.S. Preventive Services Task Force (USPSTF)[1] 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, Soltamox (tamoxifen) solution, or Evista (raloxifene) at zero dollar cost share if being used for primary prevention of breast cancer and criteria are met.

2. **Coverage Criteria:**

A. Coverage at zero dollar cost share will be approved based on **all** of the following criteria:

1. Member is greater than or equal to 35 years of age[a]

-AND-

2. Member does not have a prior diagnosis of **any** of the following:
   a. breast cancer
   b. ductal carcinoma in situ (DCIS)
   c. lobular carcinoma in situ (LCIS)

-AND-

3. Member does not have a history of thromboembolic events (e.g. deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)

-AND-

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%. [2]

-AND-

5. **One** of the following:
   a. Request is for tamoxifen 20mg once daily

-OR-

   b. Both of the following:
      i. Member is post-menopausal

-AND-

      ii. One of the following:
         (a) Request is for raloxifene 60mg once daily

-OR-

         (b) Request is for brand Evista* 60mg once daily and member has had failure, contraindication or adverse reaction to raloxifene

-OR-

   c. Both of the following:
      i. Request is for Soltamox* 20mg once daily

-AND-

      ii. Member has had failure, contraindication or adverse reaction to tamoxifen tablet

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
[a] Not applicable to plans sitused 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 5/2019
2. Assessment of Breast Cancer Risk Status. U.S. Preventive Services Task Force https://bcrisktool.cancer.gov/Accessed 5/2019
3. tamoxifen Prescribing Information. Andrx Pharmaceuticals, Inc. Ft. Lauderdale, FL February, 2003.
4. Soltamox Prescribing Information. Oncogenerix, Inc. Mt. Pleasant, SC. April 2019.
5. Evista Prescribing Information. Eli Lilly. Indianapolis, IN. June 2018.

Program	Prior Authorization/Regulatory - Breast Cancer Prevention Zero Dollar Cost Share - Tamoxifen (applies to 20 mg dose only), Soltamox (tamoxifen) solution, Evista (raloxifen)
Change Control	
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.