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 has **no** 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 has **no** 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%.  

-AND-

5. **One** of the following:
   a. Request is for tamoxifen 20mg once daily
   b. Both of the following:
      i. Member is post-menopausal
      ii. One of the following:
         (a) Request is for raloxifene 60mg once daily
         (b) Request is for Evista* 60mg once daily and member has had
            failure, contraindication or adverse reaction to raloxifene
   c. Both of the following:
      i. Request is for Soltamox* 20mg once daily
      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:**
   
   • N/A

4. **References:**

   1. U.S. Preventive Services Task Force
   3. tamoxifen Prescribing Information. Andrx Pharmaceuticals, Inc.
<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Regulatory - Breast Cancer Prevention Zero Dollar Cost Share - Tamoxifen (applies to 20 mg dose only), Soltamox (tamoxifen) solution, Evista (raloxifen)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
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<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>7/2014</td>
<td>New program.</td>
</tr>
<tr>
<td>8/2014</td>
<td>Added criteria for Evista requiring raloxifene as first line agent</td>
</tr>
<tr>
<td>5/2015</td>
<td>Updated references.</td>
</tr>
<tr>
<td>8/2015</td>
<td>Removed criterion requiring patient to be female per HCR requirements</td>
</tr>
<tr>
<td>7/2016</td>
<td>Annual review. Minor revisions to background section.</td>
</tr>
<tr>
<td>7/2017</td>
<td>Annual review. Administrative updates. Updated references.</td>
</tr>
<tr>
<td>4/2018</td>
<td>Update for District of Columbia regulatory requirements.</td>
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</table>