Criteria:
21-gene real-time polymerase chain reaction (RT-PCR) Assay (Oncotype DX®) is considered medically necessary to assess the need for adjuvant chemotherapy in women with recently diagnosed breast cancer within six months of diagnosis when ALL of the following criteria are met:

1. Breast tumor is stage 1 or stage 2, unilateral, and non-fixed. If multiple ipsilateral primary tumors are present, a specimen from only the tumor with the most aggressive histological characteristics should be submitted for testing. It is not necessary to conduct testing on each tumor; treatment is based on the most aggressive lesion.
2. Tumor size 0.6 to 1.0 cm with moderate/poor differentiation or unfavorable features (i.e., angiolymphatic invasion, high histologic grade, or high nuclear grade), OR tumor size > 1.0 cm.
3. The individual is axillary-node negative or has axillary-node micrometastasis no greater than 2.0 millimeters.
4. There is no evidence of distant metastatic breast cancer.
5. Breast tumor is estrogen-receptor positive or progesterone positive or both.
6. Breast tumor is HER2-receptor negative or breast tumor is HER2-receptor positive and less than 1 cm in diameter. (Rationale: adjuvant chemotherapy with trastuzumab (Herceptin) is considered to be medically necessary regardless of an 21-gene RT-PCR assay (Oncotype DX®) score for HER2-receptor positive lesions 1 cm or more in diameter).
7. The individual is a candidate for possible adjuvant chemotherapy (i.e., chemotherapy is not precluded due to other factors), and testing is being done specifically to guide the decision as to whether or not adjuvant chemotherapy will be used. Member and physician (prior to testing) have discussed the potential results of the test and agree to use the results to guide therapy (i.e., member will forgo adjuvant chemotherapy if 21-gene RT-PCR assay (Oncotype DX®) score is low).

All other indications for 21-gene RT-PCR assay (Oncotype DX®), including determination of recurrence risk in breast cancer patients with positive lymph nodes, use in male breast cancer, or use for recurrent or metastatic breast cancer in a patient who already has a previous 21-gene RT-PCR assay (Oncotype DX®) result are considered investigational and not a covered benefit.

HCPCS Code:
S3854
References Used:
21-gene RT-PCR assay (Oncotype DX®) product insert.
Coverage policies in effect for United Healthcare, Wellmark, Cigna, and Aetna, accessed online 9-12-12.


Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Change History:

<table>
<thead>
<tr>
<th>Change Date:</th>
<th>Changed By:</th>
<th>Description of Change:</th>
<th>New Version Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/4/13</td>
<td>Medical Director</td>
<td>Review by oncology consultant. Approved by CAC.</td>
<td>1</td>
</tr>
<tr>
<td>10/18/13</td>
<td>CAC</td>
<td>Criteria renamed with generic name of 21-gene RT-PCR (real-time polymerase chain reaction) Assay (Oncotype DX®).</td>
<td>2</td>
</tr>
<tr>
<td>7/14/15</td>
<td>Medical Director</td>
<td>Added NCCN reference.</td>
<td>3</td>
</tr>
<tr>
<td>7/17/15</td>
<td>CAC</td>
<td>Added last paragraph in References Used.</td>
<td>4</td>
</tr>
<tr>
<td>7/15/16</td>
<td>Medical Director</td>
<td>Criterion #5 added “or progesterone positive or both”.</td>
<td>5</td>
</tr>
</tbody>
</table>

C. David Smith, MD