Medical Policy
Genetic Testing for Tamoxifen Treatment

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Policy Number: 067
BCBSA Reference Number: 2.04.51

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue℠ and Medicare PPO Blue℠ Members
Genotyping to determine cytochrome p450 (CYP2D6) genetic polymorphisms for the purpose of managing treatment with Tamoxifen for women at high risk for or with breast cancer is INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO Blue℠
This is NOT a covered service.

Medicare Members: PPO Blue℠
This is NOT a covered service.
CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tr>
<td>81226</td>
<td>CYP2D6 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g., drug metabolism), gene analysis, common variants</td>
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ICD-9 Diagnosis Codes

Investigational for all diagnoses.

Description

Estrogen can promote the growth of breast cancer cells. Some breast cancers are classified as estrogen receptor-positive (also known as hormone sensitive), which means that they have a protein to which estrogen will bind. These breast cancer cells need estrogen to grow. Tamoxifen works against the effects of estrogen on these cells by interfering with its activity. Although Tamoxifen acts against the effects of estrogen in breast tissue, it acts like estrogen in other tissues and therefore side effects of blood clots, stroke and uterine cancer are possible.

Tamoxifen is prescribed to prevent or treat breast cancer in the following situations:
- For women that are at high risk for the development of breast cancer,
- To prevent a recurrence of cancer in patients who have been treated for estrogen-receptor positive breast cancer,
- As a treatment for metastatic breast cancer, or
- For women with ductal carcinoma in situ.

Tamoxifen itself has no effect against breast cancer. However, when it enters the blood stream it is acted on by an enzyme in the liver known as CYP2D6, which produces metabolites that are very active against breast cancer cells. The activity of CYP2D6 varies based on individual genetic profiles. It has been proposed that by analyzing an individual’s genetic makeup for CYP2D6, those individuals with genes that produce low activity enzymes can be identified and could forego treatment with Tamoxifen, in favor of an alternative approach. However, this theory has not been supported by evidence for determining who would and who would not benefit from Tamoxifen treatment.

Summary

The available evidence does not clearly support a significant association between CYP2D6 genotype and tamoxifen treatment outcome; an indirect evidence chain supporting the clinical utility of CYP2D6 genotyping for directing endocrine therapy regimen selection for women at high risk for or with breast
cancer cannot be constructed. Thus, because the impact of testing on net health outcome is not known, this testing is considered investigational.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>8/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
<tr>
<td>1/2009</td>
<td>Format updated. No changes to policy statements.</td>
</tr>
<tr>
<td>9/2008</td>
<td>Medical policy 067 created.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References

15. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). CYP2D6 Pharmacogenomics of Tamoxifen Treatment. TEC Assessments 2011.


