

Policy #: 067

**Original policy date: 9/1/08
Revised date: 10/8/09**

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Title

Genetic Testing for Tamoxifen Treatment

Description

Tamoxifen is a drug that is similar to the hormone estrogen and has been found to be effective in the treatment and prevention of breast cancer in several situations. It is prescribed to prevent breast cancer in 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, and for women with ductal carcinoma in situ.

Tamoxifen itself has no activity 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 considerably from person to person. Women who have an enzyme with low activity, for example, will not benefit very much from taking tamoxifen, because the concentration of the active metabolites in their systems will be low. If it were possible to identify women who are poor metabolizers, the information could be used to pursue other treatments rather than prescribing tamoxifen.

The variability in the activity of CYP2D6 from person to person is due to small differences in the genes that produce the enzyme. There are approximately 90 different versions of the gene. It has been proposed that by analyzing an individual's genes for CYP2D6, those individuals with genes that produce low activity enzymes could be identified and could forego treatment with tamoxifen, in favor of an alternative approach. However, there is little evidence to support this approach as an effective strategy for determining who would and who would not benefit from tamoxifen treatment.

When services are not covered for all Products, (including Medicare HMOB, Medicare PPO Blue, and Blue Medicare PFFS Plus Rx)

We do not cover genetic testing (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. This testing is considered investigational and therefore does not meet the BCBSMA Medical Technology Assessment Guidelines, #[350](#).

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed

Blue Cross Blue Shield of Massachusetts
 Provider Appeals
 P. O. Box 986065
 Boston, MA 02298

Prior to performance of service

Blue Cross Blue Shield of Massachusetts
 Case Creation/Medical Policy
 One Enterprise Drive
 Quincy, MA 02171
 Tel: 1-800-327-6716
 Fax: 1-888-641-5330

Managed care guidelines

No prior authorization required. Not a covered service

Indemnity and PPO guidelines

No prior authorization required. Not a covered service

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following code is 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.

CPT codes:

- **83890:** molecular diagnostic; molecular isolation or extraction
- **83891:** molecular diagnostic; isolation or extraction of highly purified nucleic acid
- **83892:** molecular diagnostic; enzymatic digestion
- **83893:** molecular diagnostic; dot/slot blot production
- **83894:** molecular diagnostic; separation by gel electrophoresis (eg, agarose, polyacrylamide)
- **83896:** molecular diagnostic; nucleic acid probe, each
- **83897:** molecular diagnostic; nucleic acid transfer (eg, Southern, Northern)
- **83898:** molecular diagnostic; amplification, target, each nucleic acid sequence
- **83900:** molecular diagnostic; amplification, target, multiplex, first two nucleic acid sequences
- **83901:** molecular diagnostic; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (list separately in addition to code for primary procedure)
- **83902:** molecular diagnostic; reverse transcription
- **83903:** molecular diagnostic; mutation scanning, by physical properties (eg, single strand conformational polymorphisms (SSCP), heteroduplex, denaturing gradient gel electrophoresis (DGGE), RNA'ase A) single segment, each
- **83904:** molecular diagnostic; mutation identification by sequencing, single segment, each segment
- **83905:** molecular diagnostic; mutation identification by allele specific transcription, single segment, each segment
- **83906:** molecular diagnostic; mutation identification by allele specific translation, single segment, each segment
- **83907:** molecular diagnostic; lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue)
- **83908:** molecular diagnostic; amplification, signal, each nucleic acid sequence
- **83909:** molecular diagnostic; separation and identification by high resolution technique (eg, capillary electrophoresis)

- **83912:** molecular diagnostic; interpretation and report
- **83913:** molecular diagnostic; RNA stabilization
- **83914:** mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay (OLA), single base chain extension (SBCE), or allele-specific primer extension (ASPE))
- **88384:** array-based evaluation of multiple molecular probes; 11 through 50 probes
- **88385:** array-based evaluation of multiple molecular probes; 51 through 250 probes
- **88386:** array-based evaluation of multiple molecular probes; 251 through 500 probes

Modifier

- **9B:** CYP2 genes, commonly called cytochrome p 450 (drug metabolism)

Other Information

For our Medical Technology Assessment Guidelines, see document #[350](#).

Policy update history

Policy issued 9/2008; BCBSMA non-coverage previously noted on Medical Policy document #365, May 2008. Reviewed 10/08 MPG – Hematology/Oncology, no changes in coverage were made. Updated 1/09 removed the Patient Information section to align with new document format. Updated 9/09 based on the BCBSA non-coverage national policy that is unchanged, which BCBSMA benchmarks. References 22 through 26 added. Reviewed 9/2009 MPG-Hematology and Oncology, no changes in coverage were made.

Footnotes and References

¹ Based on the BCBSA national policy #2.04.51, Genetic Testing for Tamoxifen Treatment, issued 7/2009.

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