Medical Policy

Gene Expression Profiling of Tumor Tissue to Predict Cancer Recurrence and Risk Stratification (Including Oncotype DX™ and Other Tests)

Policy Number: OCA 3.572
Version Number: 11
Version Effective Date: 11/01/16

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
<th>All Plan* Products</th>
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<tbody>
<tr>
<td>☑ New Hampshire Medicaid</td>
<td>☑ MassHealth</td>
<td>☑ Senior Care Options</td>
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<tr>
<td>☑ NH Health Protection Program</td>
<td>☑ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers Oncotype DX™ gene expression profiling of tumor tissue to predict breast cancer recurrence to be medically necessary for all members (regardless of gender) when medical criteria are met. **Plan prior authorization is required for all molecular and chromosomal genetic testing, including all gene expression profiling tests.** It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. See the Plan policy, **Medically Necessary** (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment.
The Plan only covers gene expression profiling testing for breast cancer recurrence with the Oncotype DX™; the use of Oncotype DX™ for any other indication, to predict recurrence for any other type of cancer, or when Plan criteria are not met is considered investigational. Other types of gene expression profiling tests used to predict breast cancer recurrence or used to predict other types of cancer recurrence or risk stratification are considered investigational; see Plan policy, Genetic Testing Guidelines and Pharmacogenetics (policy number OCA 3.727), for gene expression testing to predict response to drug therapy and treatment and/or to classify a tumor into a main cancer type and subtype. Review the Plan policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental and investigational treatment.

The Plan supports the National Comprehensive Cancer Network (NCCN) guidelines for genetic counseling for all genetic tests conducted with Plan members; NCCN recommends that adequate pre-test and post-test genetic counseling be provided by a health care professional with expertise in genetics. Genetic counseling provided to a Plan member (and/or guardian if the member is under the age of 18) should be documented in the member’s medical record and conducted by an appropriately trained practitioner with expertise and experience in genetics, including a provider acting within the scope of the practitioner’s license and practice, clinical geneticist, or genetic counselor.

Plan prior authorization is required for all molecular and chromosomal genetic testing, except for prenatal genetic screening tests when the member is pregnant (as specified in the Applicable Coding section of this policy) and Plan criteria are met. See the following Plan policies for additional prior authorization guidelines for genetic testing available at www.bmchp.org for BMC HealthNet Plan members (or at www.SeniorsGetMore.org for Senior Care Options members) and www.wellsense.org for Well Sense Health Plan members:

1. Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies, policy number OCA 3.573
2. Genetic Testing for Familial Malignant Melanoma, policy number OCA 3.78
3. Genetic Testing for Fragile X-Associated Disorders, policy number OCA 3.571
4. Genetic Testing Guidelines and Pharmacogenetics, policy number OCA 3.727
5. Genetic Testing for Hereditary Breast and Ovarian Cancer, policy number OCA 3.57
6. Genetic Testing for Hereditary Colorectal Cancer, policy number OCA 3.64
7. Genetic Testing for Hereditary Thrombophilia, policy number OCA 3.728
8. Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Pregenetic Screening), policy number OCA 3.726
Description of Item or Service

Gene Expression Profiling/Genomic Assay: A laboratory test that measures the expression of a group of genes and translates the gene expression information into a risk score for a given disease or condition (e.g., recurrence of primary breast cancer). Genetic tests can estimate an individuals’ risk of developing a disease in the future. Gene expression tests measure the activity of RNA in a tissue or bodily fluid at a given point in time to provide information on the individual’s current disease state, predict an individual’s response to treatment, or predict the likelihood of future disease with risk stratification; RNA levels change over time based on pathological conditions and environmental signals.

Oncotype DX™ Breast Cancer Assay: A multiple gene expression assay of 21 genes performed on tumor tissue from individuals with newly diagnosed, early-stage (stage 1 or II), estrogen receptor positive (ER+), node negative (N-) breast cancer to predict the risk of recurrence. The assay is used to guide use of adjuvant tamoxifen and adjuvant chemotherapy. Formalin-fixed paraffin-embedded (FFPE) tumor samples are analyzed, measuring the messenger (mRNA) expression levels of 16 genes which are markers for proliferation and recurrence; test results are used to quantify the probability of breast cancer recurrence.

Medical Policy Statement

The Plan considers Oncotype DX™ (Genomic Health) gene expression profiling of tumor tissue to predict breast cancer recurrence to be medically necessary for all members (regardless of gender) when ALL of the following criteria are met and documented in the medical record, as specified below in items 1 through 6:

1. The Oncotype DX™ is ordered by the physician supervising the adjuvant therapy; AND

2. Tumor is unilateral and non-fixed; AND

3. Disease is stage I or II; AND

4. There is no evidence of distant metastatic breast cancer; AND

5. The member is a candidate for adjuvant chemotherapy and testing is being done specifically to guide the decision as to whether or not adjuvant chemotherapy will be used; AND

6. The tumor has ALL of the following characteristics based on post-operative pathological evaluation, as specified below in items a through h:
Gene Expression Profiling of Tumor Tissue to Predict Cancer Recurrence and Risk Stratification

Inoculating ductal; OR
(2) Infiltrating lobular; OR
(3) Metaplastic; OR
(4) Mixed; AND

Histology of tumor is not tubular or colloid; AND

Lymph node status meets ONE (1) of the following criteria, as specified below in items (1) through (3):

(1) Axillary-node negative; OR
(2) Axillary-node micrometastasis is no greater than 2.0 millimeters; OR
(3) 1 to 3 involved ipsilateral axillary lymph nodes to guide the addition or combination chemotherapy to standard hormone therapy; AND

Tumor size is greater than 0.5 cm in diameter; AND

Tumor is unifocal; AND

Hormone receptor positive (i.e., estrogen receptor positive [ER+] AND/OR progesterone receptor positive [PR+]); AND

Human epidermal growth factor receptor 2 (HER2/neu) negative; AND

Tumor is not a pT4 lesion

Limitations

1. Repeat Oncotype DX™ testing and/or testing of multiple tumor sites in the same person are not considered medically necessary.

2. Oncotype DX™ testing for indications other than those listed in the Medical Policy Statement section is not considered medically necessary (e.g., Oncotype DX™ Colon Cancer Assay and Oncotype DX Prostate Cancer Assay).

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3. Oncotype DX™ testing for the prognosis of recurrence of ductal carcinoma in situ (DCIS) breast cancer is not considered medically necessary.

4. The Oncotype DX™ is the only test considered medically necessary for gene expression profiling of breast cancer tissue when Plan criteria are met; other gene expression profiling tests of breast cancer tissue are considered either investigational or not medically necessary as an alternative to Oncotype DX, including but not limited to BluePrint™, Breast Cancer Index (BCI) by bioTheranostics Inc., Ki-67 (MKI67) proliferation marker testing, MammaPrint®, and/or the Prosigna™ Breast Cancer Prognostic Gene Signature Assay.

5. Other types of gene expression profiling tests used to predict recurrence of any type of cancer or determine risk stratification are considered investigational based on the guidelines in this Plan policy; examples of these investigational tests include Afirma Thyroid FNA Analysis (Veracyte Inc.), DecisionDx-GBM for glioblastoma multiforme (Castle Biosciences Inc.), DecisionDx-Melanoma (Castle Biosciences Inc.), DecisionDx-UM for uveal melanoma (Castle Biosciences Inc.), and MyPRS™ Plus (Signal Genetics LLC) for myeloma. See Plan policy, Genetic Testing Guidelines and Pharmacogenetics (policy number OCA 3.727), for gene expression testing to predict response to drug therapy and treatment and/or for genetic testing to identify the primary tissue of origin in a member when there is clinical uncertainty of a tumor’s primary origin.

Definitions

Breast Cancer Staging:

1. Stage I: Early stage cancer that is less than 2 cm wide and hasn’t spread beyond the breast.

2. Stage II: Early stage cancer in which the tumor is: no larger than 2 cm wide and has spread to the lymph nodes under the arm, between 2 and 5 cm wide and may or may not have spread to the lymph nodes under the arm, or larger than 5 cm and hasn’t spread outside the breast.

3. Stage III: Locally advanced breast cancer in which the tumor is: greater than 5 cm wide and has spread to the lymph nodes under the arm, extensive in the underarm lymph nodes, or spreading to lymph nodes near the breastbone or to other tissues near the breast. (Note: Recurrent breast cancer or bilateral breast cancer is categorized as stage III or stage IV according to the National Comprehensive Cancer Network.)

4. Stage IV: Metastatic breast cancer that has spread outside the breast to other organs in the body, such as the bones, lungs, liver, or brain. (Note: Recurrent breast cancer or bilateral breast cancer is categorized as stage III or stage IV according to the National Comprehensive Cancer Network.)
**Fluorescence In Situ Hybridization (FISH):** A test that maps specific genes or portions of genes. FISH testing is done on breast cancer tissue removed during biopsy to see if the cells have extra copies of the HER2 gene. The more copies of the HER2 gene that are present, the more HER2 receptors the cells have. These HER2 receptors receive signals that stimulate the growth of breast cancer cells. The FISH test results will determine if the cancer is either “positive” or “negative” (a result sometimes reported as “zero”) for HER2. Generally, the FISH test is not as widely available as another method of HER2 testing, called immunohistochemistry, or IHC. However, FISH is considered more accurate. In many cases, a lab will do the IHC test first, ordering FISH only if the IHC results don’t clearly show whether the cells are HER2-positive or negative.

**Formalin Fixed Paraffin-Embedded (FFPE) Tumor Tissue:** Tissue samples derived from tissues (usually suspected tumor samples) that are fixed with formalin to preserve the cytoskeletal and protein structure and then embedded in a type of paraffin wax so the tissue can be sliced on a microtome, an instrument used to prepare very fine slices. Formalin irreversibly cross-links proteins via the amino groups thus preserving the structural integrity of the cells so they can be stained with dyes used to analyze for abnormalities in the tissue that indicate cancer.

**Genetic Testing:** According to U.S. Library of Medicine, genetic testing is defined as a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person’s chance of developing or passing on a genetic disorder. More than 1,000 genetic tests are currently in use, and more are being developed. Several methods can be used for genetic testing:

1. Molecular genetic tests (or gene tests) study single genes or short lengths of DNA to identify variations or mutations that lead to a genetic disorder.

2. Chromosomal genetic tests analyze whole chromosomes or long lengths of DNA to see if there are large genetic changes, such as an extra copy of a chromosome, that cause a genetic condition.

3. Biochemical genetic tests study the amount or activity level of proteins; abnormalities in either can indicate changes to the DNA that result in a genetic disorder.

**Immunohistochemistry (IHC):** A special staining process performed on fresh or frozen breast cancer tissue removed during biopsy. IHC is used to show whether or not the cancer cells have HER2 receptors and/or hormone receptors on their surface. This information plays a critical role in treatment planning. The IHC test gives a score of 0 to 3+ that measures the amount of HER2 receptor protein on the surface of cells in a breast cancer tissue sample. If the score is 0 to 1+, it’s called “HER2 negative.” If the score is 2+, it's called "borderline." A score of 3+ is called “HER2 positive.”
**pT4 Pathologic Staging of Breast Tumor:** Breast tumor of any size with direct extension to chest wall or skin. Clinical information may be required to designate a tumor as pT4. Dermal invasion alone (without ulceration, satellite nodules, or inflammatory breast cancer) does not alter T category; such cases are classified as T1, T2, or T3, depending on tumor size. pT4 is categorized as:

1. **pT4a:** Extension to chest wall, not including pectoralis muscle
2. **pT4b:** Edema (including peau d’orange) or ulceration of the skin of the breast or satellite skin nodules confined to the same breast
3. **pT4c:** Both T4a and T4b
4. **pT4d:** Inflammatory carcinoma

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines. Review the Plan’s policy, *Genetic Testing Guidelines and Pharmacogenetics*, policy number OCA 3.727, for additional guidelines regarding genetic testing. **Plan prior authorization is required for all molecular and chromosomal genetic testing unless otherwise specified in an applicable Plan medical policy.**
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code Covered When Medically Necessary</th>
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<tbody>
<tr>
<td>81519</td>
<td>Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score</td>
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Plan note: Use this code when billing for the Oncotype DX™ Breast Cancer Assay.

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<thead>
<tr>
<th>HCPCS Code</th>
<th>Description: Code Covered When Medically Necessary</th>
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<tr>
<th>CPT Code</th>
<th>Description: Code Considered Experimental and Investigational</th>
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<tr>
<td>81525</td>
<td>Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score</td>
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<th>HCPCS Code</th>
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<tbody>
<tr>
<td>S3854</td>
<td>Gene expression profiling panel for use in the management of breast cancer treatment</td>
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</table>

Plan note: Use this code when billing for all gene expression profiling tests of breast cancer tissue except the Oncotype DX™ Breast Cancer Assay.

**Clinical Background Information**

Oncotype DX™ Breast Cancer Assay is used to quantify the likelihood of distant recurrence in an individual with breast cancer, and can be helpful in determining whether or not a patient is a candidate for chemotherapy. The test is recommended to be conducted after the original breast cancer surgery. RNA is extracted from the tumor tissue, purified and analyzed for expression of a panel of 21 genes using quantitative reverse transcription polymerase chain reaction (RT-PCR) on formalin-fixed, paraffin-embedded tumor tissue. The score is calculated from the gene expression results using a proprietary Oncotype DX™ algorithm and is based on a scale of 0–100. A score of less than 18 is considered low risk, a score between 18 and 31 is intermediate risk, and a score over 31 is high risk. Each score correlates with a specific likelihood of distant recurrence at 10 years.

The MammaPrint® (Agendia Inc.) assay uses a microarray technology platform to analyze the expression of 70 genes from tumor samples that are fresh frozen or placed in an RNA molecular fixative solution provided in a kit from the manufacturer. Agendia now accepts formalin-fixed paraffin-embedded (FFPE) specimens for analysis in addition to fresh frozen samples. In the United States, the MammaPrint® assay is intended for patients with breast cancer who are stage I or II, have lymph node negative, and have a tumor size < 5.0 centimeters (cm). Additional indications for MammaPrint® used outside of the United States include patients who are estrogen receptor positive (ER+) or negative (ER-) and patients who are either lymph node positive or negative. Currently, the Plan...
considers this test to not be medically necessary as an alternative to Oncotype DX™ (the 21-gene assay). According to the National Comprehensive Cancer Network (NCCN) Version 1.2016 Breast Cancer Guidelines, “the NCCN Panel members acknowledge that many assays, including PAM50 and MammaPrint, have been clinically validated for prediction of prognosis. However, based on the current available data, the panel believes that the 21-gene assay has been best-validated for its use as a prognostic test as well as in predicting who is most likely to respond to systemic chemotherapy.”

The BluePrint® molecular subtyping profile is an 80-gene expression profile that is designed to characterize breast tumors as basal-type, luminal-type, and ERBB2 (commonly referred to as HER2/neu )-type breast cancers. The manufacture (Agendia Inc.) claims that BluePrint® complements the MammaPrint® to allow for a more refined prediction of distant recurrence in patients at increased risk of recurrence by MammaPrint® and validates the prediction of low risk or recurrence by MammaPrint®. The Plan considers this test experimental and investigational.

Prosigna™ Breast Cancer Prognostic Gene Signature Assay (NanoString Technologies Inc.) is used with female breast cancer patients (as defined by the manufacturer) who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. The test is a prognostic indicator for distant recurrence–free survival at 10 years in postmenopausal women (as defined by the manufacturer)with hormone receptor positive (HR+), lymph node negative or lymph node positive (up to 1-3 positive nodes), stage I or II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors. The Plan considers the test investigational at this time. Prosigna is performed using messenger RNA (mRNA) isolated from formalin-fixed paraffin-embedded (FFPE) breast tumor specimens or tissue slides. The set of 46 genes included in the assay is based upon PAM50, a 50-gene expression classifier that distinguishes between intrinsic breast cancer tissue subtypes that are associated with different rates of recurrence.

The Food and Drug Administration (FDA) only regulates genetic tests sold as kits and has practiced enforcement discretion for laboratory-developed tests (LDTs), which represent the majority of genetic tests marketed in the United States. While the Centers of Medicare & Medicaid Services (CMS) does regulation the clinical laboratories in which LDTs are performed, CMS does not evaluate whether the genetic tests are clinically meaningful.

References


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<th>Original Approval Date</th>
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<th>Policy Owner</th>
<th>Approved by</th>
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<tr>
<td>Regulatory Approval: N/A</td>
<td>02/01/12 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
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<tr>
<td>Internal Approval: 10/19/11: MPCTAC 11/29/11: QIC</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

**Policy Revisions History**

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<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tr>
<td>07/01/12</td>
<td>Off cycle review of Well Sense Health Plan, revised Summary section, reformatted Medical Policy Statement section, deleted diagnosis codes, revised language in Applicable Coding section.</td>
<td>Version 2</td>
<td>08/03/12: MPCAC 09/05/12: QIC</td>
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<tr>
<td>09/01/12</td>
<td>Review for effective date 01/01/13. Revised policy title, specified in Summary section that Plan prior authorization is required and referenced the Plan’s Medically Necessary policy and the Experimental and Investigational Treatment policy, updated language in Applicable Coding section, removed diagnosis codes because diagnosis codes do not change prior authorization requirement, updated and added references. Added limitation on testing of multiple tumor sites in the same person.</td>
<td>01/01/13 Version 3</td>
<td>09/19/12: MPCTAC 10/24/12: QIC</td>
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<tr>
<td>08/14/13 and 08/15/13</td>
<td>Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 09/01/12 (as specified above) for the Well Sense Health Plan product; these</td>
<td>Version 4</td>
<td>08/14/13: MPCTAC (electronic vote) 08/15/13: QIC</td>
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<tr>
<td>10/01/13</td>
<td>Review for effective date 02/01/14. Revised title, Summary section, and Limitations section. Revised criteria in the Medical Policy Statement section. Updated Definitions section and references. Added Plan note to the Applicable Coding section.</td>
<td>02/01/14</td>
<td>10/16/13</td>
<td>MPCTAC 11/21/13: QIC</td>
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<td>08/01/14</td>
<td>07/21/14</td>
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<td>10/01/14, 11/01/14, and 12/01/14</td>
<td>Review for effective date 03/01/15. Revised Summary, Description of Item or Service, Clinical Background Information, and References sections. Updated criteria in the Medical Policy Statement and Limitations sections. Revised title to include “Risk Stratification.” Added CPT code 81519 as an applicable code.</td>
<td>03/01/15</td>
<td>10/15/14</td>
<td>MPCTAC 11/12/14: QIC 12/02/14: MPCTAC (electronic vote) 12/10/14: QIC</td>
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<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/18/15</td>
<td>MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
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<td>01/01/16</td>
<td>Annual review for effective date 05/01/16. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Summary, Description of Item or Service, Clinical Background Information, and References sections. Revised the applicable code list.</td>
<td>05/01/16</td>
<td>01/20/16</td>
<td>MPCTAC 02/10/16: QIC</td>
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<td>Industry-wide addition of applicable HCPCS code S3854 effective 07/01/16.</td>
<td>07/01/16</td>
<td>Not applicable</td>
<td>because industry-wide code addition.</td>
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<td>09/28/16</td>
<td>Review for effective date 11/01/16. Administrative changes made to clarify language related to gender.</td>
<td>11/01/16</td>
<td>09/30/16</td>
<td>MPCTAC 10/12/16: QIC (electronic vote)</td>
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