

FEBRUARY 2018

KMAP GENERAL BULLETIN 18047

Gene Expression Profiling

Effective with date of service on and after, March 1, 2018, the Kansas Medical Assistance Program (KMAP) will consider the following for coverage:

1. The use of the 21-gene reverse transcriptase-polymerase chain reaction (RT-PCR) assay that is not considered experimental or investigational (such as Oncotype DX[®], EndoPredict[®], Breast Cancer IndexSM, and Prosigna[®]) to determine recurrence risk for deciding whether to undergo adjuvant chemotherapy may be considered **medically necessary** in individuals with primary, invasive breast cancer meeting **ALL** of the following characteristics:
 - a. Unilateral tumor
 - b. Hormone receptor-positive (that is, estrogen-receptor [ER]-positive or progesterone receptor [PR]-positive)
 - c. Human epidermal growth factor receptor 2 (HER2) – negative
 - d. Tumor size 0.6 to 1 cm with moderate/poor differentiation or unfavorable features OR tumor size larger than 1 cm
 - e. Node negative (lymph nodes with micrometastases [less than 2 mm in size] are considered node negative for this policy statement)
 - f. Will be treated with adjuvant endocrine therapy, e.g. tamoxifen or aromatase inhibitors
 - g. When the test result will aid the patient in making the decision regarding chemotherapy (e.g. when chemotherapy is a therapeutic option)
 - h. When ordered within six months following diagnosis, since the value of the test for making decisions regarding delayed chemotherapy is unknown
2. The 21-gene RT-PCR assay Oncotype DX should only be ordered on a tissue specimen obtained during surgical removal of the tumor and after subsequent pathology examination of the tumor has been completed and determined to meet the above criteria (e.g. the test should not be ordered on a preliminary core biopsy). The test should be ordered in the context of a physician-patient discussion regarding risk preferences when the test result will aid in making decisions regarding chemotherapy.
3. For patients who otherwise meet the above characteristics but who have multiple ipsilateral primary tumors, a specimen from 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.

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Gene Expression Profiling

4. The use of gene expression assays in men with breast cancer is considered medically necessary.
5. All other indications for the 21-gene RT-PCR assay (e.g. Oncotype DX), including determination of recurrence risk in invasive breast cancer patients with positive lymph nodes or patients with bilateral disease, are considered experimental/investigational.
6. All other indications for the 21-gene RT-PCR assay (e.g. Oncotype DX, EndoPredict, Breast Cancer Index, and Prosigna) including determination of recurrence risk in invasive breast cancer patients with positive lymph nodes, patients with bilateral disease, or to consider length of treatment with tamoxifen, are considered experimental/investigational.
7. Use of a subset of genes from the 21-gene RT-PCR assay for predicting recurrence risk in patients with noninvasive ductal carcinoma in situ (e.g. Oncotype DX, Breast DCIS Score) to inform treatment planning following excisional surgery is considered experimental/investigational.
8. Use of 70-gene signature (MammaPrint®) for any indication is considered experimental/investigational.
9. The use of Blueprint® in conjunction with MammaPrint or alone is considered experimental/investigational.
10. Repeat gene expression profiling for the same tumor (for example a metastatic focus) or from more than one site when the primary tumor is multifocal is considered investigational and not medically necessary.

CPT® codes: 81519 and 81599

Diagnosis codes: C50011, C50012, C50021, C50022, C50111, C50112, C50211, C50212, C50311, C50312, C50411, C50412, C50511, C50512, C50611, C50612, C50811, C50812, and Z170

Note: Genetic testing is covered only when documentation supports signs and/or symptoms of an inherited disease in the affected individual; there has been a physical examination, pretest counseling, and other diagnostic studies; and the determination of the diagnosis in the absence of such testing remains uncertain and would impact the care and management of the individual on whom the testing is performed.

Gene expression profiling as a technique of managing the treatment of breast cancer will be limited to one test per breast cancer diagnosis.

Note: The effective date of the policy is March 1, 2018. The implementation of State policy by the KanCare managed care organizations (MCOs) may vary from the date noted in the KMAP bulletins. The **KanCare Open Claims Resolution Log** on the KMAP [Bulletins](#) page documents the MCO system status for policy implementation and any associated reprocessing completion dates, once the policy is implemented.

For the changes resulting from this provider bulletin, view the updated *Professional Fee-for-Service Provider Manual*, Section 8400, pages 8-30 and 8-31.

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