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Improving decision making…
to improve outcomes

Castle Biosciences Announces Medicare Coverage for the DecisionDx-Melanoma Test in Cutaneous Melanoma

Palmetto GBA issues final local coverage determination effective December 3, 2018

Friendswood, Texas – Oct 18, 2018 – Castle Biosciences, Inc., the skin cancer diagnostics company providing molecular diagnostics to improve cancer management decisions, today announced Medicare coverage for the DecisionDx®-Melanoma test that predicts risk of metastatic disease and helps to guide use of sentinel lymph node biopsy (SLNB) in patients with cutaneous melanoma.

"Improved access to the DecisionDx-Melanoma test for the 59 million Medicare recipients can drive better-informed management decisions for melanoma patients and help to safely avoid costly surgical procedures," said Derek Maetzold, President and CEO of Castle Biosciences. "Using the DecisionDx-Melanoma test to identify low-risk tumor biology and inform the discussion of SLNB options provides an important advance in the management of early stage melanoma patients."

Palmetto GBA, a Medicare Administrative Contractor (MAC), the administrator of the Medicare MolDX® program that assesses molecular diagnostic technologies, issued a final local coverage determination (LCD) for the DecisionDx-Melanoma test effective December 3, 2018. Medicare beneficiaries will now have improved access to the test to help guide use of SLNB in the context of patient-specific management plans. The LCD provides for coverage of the DecisionDx-Melanoma test for SLNB eligible patients with T1 and T2 cutaneous melanoma tumors (2.0 mm in thickness or less, as defined in AJCC Staging Manual v8, 2017) and clinically negative sentinel node basins who are being considered for SLNB to determine eligibility for adjuvant therapy.

Approximately 12,000 patients had the DecisionDx-Melanoma test ordered in the last 12 months to better inform patient management decisions and help guide their melanoma care. This is an important milestone for the test, which is supported by more than 15 peer-reviewed publications including analytic and clinical validation, performance studies, and clinical utility in prospective and retrospective studies.

The final LCD is posted to the Medicare Coverage Database on the Centers for Medicare and Medicaid Services (CMS) website.

The DecisionDx-Melanoma test is a 31-gene expression profile (GEP) that determines a cutaneous melanoma patient's risk for metastatic disease. The test classifies patients as having a tumor with low (Class 1) or high (Class 2) risk for developing metastasis within 5 years of diagnosis. Patients with a Class 1 tumor profile also have a low likelihood of being SLN positive. Thus, the individualized risk profile result of this test can be used to guide use of SLNB in the context of patient-specific management plans.

The use of the DecisionDx-Melanoma test to inform SLNB decision-making was validated in two multicenter, prospective cohorts totaling 1,421 patients which showed that a Class 1A test result can identify a population with a >95% likelihood of a negative SLNB (>95% negative predictive value [NPV]). For the Medicare-eligible population (65 years old and over), patients with a T1 or T2 tumor and a DecisionDx-Melanoma Class 1A result have an NPV of 98.4%. Data from retrospective studies has shown that patients with a Class 1A result have a 99.6% melanoma-specific survival rate at 5 years. Thus, the DecisionDx-Melanoma test can inform SLNB decision-making by identifying a group of patients with low-risk tumor biology who are less than 5% likely to be SLN positive. These patients have a very low likelihood for metastatic disease, and thus can safely avoid this surgical procedure, potentially reducing the SLNB rate by up to 52% in the Medicare population.

Sentinel Lymph Node Biopsy Background
SLNB is a surgical procedure generally recommended to assess prognosis of cutaneous melanoma patients. The procedure provides prognostic information and can determine eligibility for adjuvant therapies, but can be associated with complications, adding a significant economic burden to the healthcare system. Elderly patients account for a substantial proportion of patients with melanoma, and 60% of melanoma-related deaths occur in patients 65 years of age or older. However, while older age is associated with a poor prognosis, fewer elderly patients are found to be SLN positive, which indicates that the prognostic value of SLNB is limited in this population.

Current guidelines recommend that clinicians discuss and/or offer the SLNB procedure with patients who have a greater than 5% likelihood of SLN positivity, and do not recommend the procedure if a patient has a less than 5% likelihood of a positive SLN. For patients who are SLNB eligible, the DecisionDx-Melanoma test can inform SLNB decision-making by identifying a group of patients with low-risk tumor biology who are less than 5% likely to be SLN positive, and thus can safely avoid the procedure.

About DecisionDx-Melanoma
The DecisionDx-Melanoma test uses tumor biology to predict individual risk of melanoma recurrence and sentinel lymph node positivity independent of traditional factors. Using tissue from the primary melanoma, the test measures the expression of 31 genes. The test has been validated in three multi-center studies that have included 690 patients and have demonstrated consistent results. Performance has also been confirmed in four prospective studies including 702 patients. The consistent high performance and accuracy demonstrated in these studies, which combined have included over 1,300 patients, provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results.

Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multicenter studies that included over 1,400 patients. Impact on patient management plans for one of every two patients tested has been demonstrated in multi-center and single-center studies. More information about the test and disease can be found at www.SkinMelanoma.com.

About Castle Biosciences
Castle Biosciences is a molecular diagnostics company dedicated to helping patients and their physicians make the best possible decisions about their treatment and follow up care based on the individual molecular signature of their tumor. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx®-Melanoma, DecisionDx®-CM*Seq*; www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UM*Seq*; www.MyUvealMelanoma.com), with development programs in other underserved cancers, the most advanced of which is focused on patients with cutaneous squamous cell carcinoma. Castle Biosciences is based in Friendswood, Texas (Houston), and has laboratory operations in Phoenix, Arizona. More information can be found at www.CastleBiosciences.com.

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