DecisionDx-UM Fact Sheet

Talk To Your Doctor

In this difficult time, it's important to talk to your doctor about all possible treatment options for your eye cancer as well as any questions you might have about prognostic testing.

This downloadable sheet can help guide that discussion and provide your physician with the information he or she needs to help you make a decision about whether the DecisionDx®-UM test is right for you.

DECISIONDx-UM BACKGROUND

What is DecisionDx-UM?

The DecisionDx-UM gene expression profile (GEP) test was developed to predict the five-year metastatic risk for uveal melanoma patients, regardless of how the primary tumor is treated. The test requires a very small sample of the tumor for laboratory analysis. It is important to note that if the treatment plan is radiation, the biopsy must be conducted prior to the radiation procedure. Castle Biosciences is the only laboratory that performs this test.

Before the test's introduction in December 2009, patients were mostly assigned a single surveillance plan, with strong potential for either under-treatment or over- treatment. The GEP test enables individualization of a patient's monitoring and management plan.

The DecisionDx-UM test is "standard of care" in the management of uveal melanoma for the majority of U.S. ocular oncologists.

Since its clinical availability, the DecisionDx-UM test has been adopted as standard of care in the management of uveal melanoma by a majority of ocular oncologists in the U.S.

The National Comprehensive Cancer Network (NCCN), a group of the most recognized and respected comprehensive cancer centers in the U.S., recommends that the clinical utility of tumor markers in oncology be determined in a prospective clinical trial, similar to the type of study required for new drugs (Febbo, 2011). Though the NCCN has not specifically evaluated DecisionDx-UM, it is the only prognostic test in uveal melanoma that would meet this strict standard for the highest level of evidence as it is the only such test to be validated in a prospective, multi-center study.

Additionally, the American Joint Committee on Cancer recommends gene expression profile testing for use as the results are "clinically significant." The American Joint Committee on Cancer (AJCC, version 8, 2017) is the only international organization that reviews uveal melanoma and the DecisionDx-UM test is the only clinically available gene expression profile test for use in the U.S.

CLINICAL DATA

The DecisionDx-UM test accurately predicts 5-year metastatic risk in patients with uveal melanoma.

By identifying the molecular signature of an individual's tumor, DecisionDx-UM accurately predicts which patients with uveal melanoma are at low and high risk of metastasis within five years, the period for which scientific data has been collected. Specifically, the assay determines the activity or "expression" of 15 genes which indicates a patient's individual risk, or class.

The DecisionDx-UM test is superior to all other prognostic factors.

DecisionDx-UM is the only prognostic test for uveal melanoma that has been clinically validated for accuracy in an independent prospective study.

According to the 494-patient study conducted by the Collaborative Ocular Oncology Group (COOG), the DecisionDx-UM test is clinically and statistically superior to all other prognostic factors in predicting metastatic risk–including clinical factors, pathologic factors, and chromosome 3 testing (Onken, 2012).

Formal statistical comparisons (using net reclassification improvement) at the three-year mark in the COOG study showed the DecisionDx-UM test to have a 43% improvement over physical characteristics and a 38% improvement over chromosome 3 testing.

The DecisionDx-UM test reports Class 1A, 1B, and 2 phenotype.

The DecisionDx-UM test is individualized to the patient's tumor and reports the following tumor classes:

Class 1A: Low risk, with a 2% chance of the eye cancer spreading over the next five years;
Class 1B: Intermediate risk, with a 21% chance of metastasis within five years;
Class 2: High risk, with 72% odds of metastasis over five years.

At 97%, the DecisionDx-UM test has a high technical success rate.

The COOG study reported a technical success rate of 97% for samples collected from pre-plaque fine-needle aspirate biopsies and formalin-fixed paraffin embedded (FFPE) samples from enucleation procedures. This level of technical success has also been seen with the clinical use of the DecisionDx-UM test. Specifically, through mid-2016, the reporting success rate was found to be 96.3% in more than 5,500 patients tested clinically (Plasseraud et al., 2017).

VALUE OF PREDICTING METASTASIS

Physicians use DecisionDx-UM to make important choices about their patients' care.

Physicians are using DecisionDx-UM to:

- **Develop patient specific surveillance plans.** Patients at high risk of developing metastasis may receive an intensive surveillance plan including frequent CT scans or MRIs, while low risk patients may be recommended less intensive monitoring. Knowing the patient's odds of metastasis can help the physician determine if the risks and cost of radiation exposure outweigh the benefits.
- **Initiate referral to a medical oncologist** for treatment planning and options which may include adjuvant treatment, and;
- **Refer appropriate high-risk patients to clinical trials.** Castle Biosciences can also provide physicians with a list of adjuvant clinical trials that might be relevant for Class 2 patients.

HOW TO ORDER

DecisionDx-UM test can only be ordered by a licensed physician.
The test requires a tumor sample, which can be obtained by fine needle aspirate biopsy (FNAB) prior to undergoing radiation, or from formalin-fixed paraffin embedded (FFPE) samples in the case of enucleation. For patients receiving radiation treatment, the timing of the biopsy is critical and the sample must be taken prior to surgery. The sample is sent to Castle Biosciences' laboratory for processing and takes 2-3 weeks to produce a result after receipt.

If your physician is a new customer to Castle, then we request that your physician's office call Castle's Customer Service **(866-788-9007)** to review the ordering and shipping process prior to the placement of an order. This should eliminate errors or omissions in the collection and transport of the specimens.

REIMBURSEMENT

Castle's Patient Access Team can help with insurance information and financial assistance services. Castle will submit insurance claims for DecisionDx-UM testing and track the claim throughout the process. Castle offers an industry-leading financial assistance program for both insured and uninsured patients. For more information regarding billing and to qualify for financial assistance, call 866-788-9007 and select option #3.

OTHER TESTS FOR UVEAL MELANOMA

Patients who are having the DecisionDx-UM GEP test performed can also have additional, optional testing performed:

- **DecisionDx®-PRAME** measures expression of the PRAME gene; tumors that exhibit positive PRAME expression may have an elevated risk of metastasis.
- **DecisionDx®-UM*Seq*** is a 7-gene sequencing panel that identifies somatic DNA mutations that could be important in the future as uveal melanoma research and treatments evolve.

MORE INFORMATION

For more information about DecisionDx-UM, please visit
www.myuvealmelanoma.com
or
call Castle Biosciences at
866-788-9007.