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Consumer Marketing of Genetic Testing for Breast Cancer

The history of genetic testing for breast cancer is short and controversial. Two genes associated with hereditary breast and ovarian cancer, BRCA1 and BRCA2, were discovered in the 1990s through an international research collaboration. Although the NIH partially funded the research, the United States Patent and Trademark Office granted exclusive patent rights to Myriad Genetics, a privately owned biotech company. Since obtaining the patent, Myriad has refused to license testing to any other company or laboratory. All BRCA1 and 2 testing in the United States is done by Myriad; no other laboratory can provide confirmatory testing.

Myriad Genetics recently launched a Direct to Consumer (DTC) marketing campaign in our region that widely promotes BRCA1 and 2 testing. As the patent holder and sole source for testing it is questionable whether Myriad can present a balanced view of appropriate use. Bioethicist Arthur Caplan denounced Myriad's DTC campaign because it exploits public anxiety about breast cancer and misleads consumers into believing that all women need these expensive tests. The "*Be Ready Against Cancer Now*" campaign uses the phrases "reduce my cancer risk now" and "cancer doesn't have to be inevitable", implying that testing alone can reduce a woman's risk. Ads in medical journals exaggerate and oversimplify benefits of testing by urging physicians to "empower your patients", promising that "together you can change the course of hereditary cancer", and "heredity doesn't have to be destiny".

Only 10% of all breast cancer is hereditary and less than 1% of the general population is estimated to carry a BRCA1 or BRCA2 mutation. A population-based marketing strategy is extremely inappropriate, since it encourages all women to demand a genetic test that is not medically indicated for most. Some insurers cover Myriad's charge for testing. At over \$3000, it is almost twice what academic laboratories were charging for BRCA1 and 2 testing prior to patenting. However,

widespread insurance claims may induce insurers to tighten their allowable criteria, making it more difficult for patients who actually need these tests to qualify for coverage.

Advertisements for genetic testing are not subject to federal regulations that govern marketing of prescription drugs. They can overstate the benefits and utility of genetic testing while failing to address the risks, limitations and uncertainties. These advertisements portray empowered, autonomous women using genetic test results to make informed decisions about the risks they face. In reality, a national patient support and advocacy group, Facing Our Risk of Cancer Empowered (FORCE), reports increased calls from anxious women in areas where the Myriad DTC marketing campaign has been underway. Women who have had DTC genetic testing without benefit of professional genetic counseling have been told their mutation was a normal result, their normal result was a mutation, or that a genetic variant of unknown significance was disease-causing.

Genetic testing is among the most important pieces of medical information conveyed to patients, and carries considerable risk of liability. Involvement of a qualified genetic counseling professional is a key component for both patients and physicians, to ensure that informed consent is obtained and complex genetic information is interpreted appropriately. Telephone counseling provided by employees of the testing laboratory, as Myriad recommends, cannot be considered adequate.

In May of this year a lawsuit against Myriad Genetics was filed on behalf of five cancer patients who initially sought confirmatory testing for their BRCA1 and 2 test results. The suit contends that gene patents interfere with a free flow of medical information and knowledge and that patents on human genes are illegal under patent law because genes are products of nature. The lawsuit is supported by professional organizations of pathologists with over 100,000 members and virtually all major professional and scientific laboratory organizations.

Physicians should provide support and encouragement to patients who may be anxious about their risk of breast or ovarian cancer. Professional genetic counseling can effectively assess individual risk factors and determine whether such testing is appropriate. It is important to remember that federal and state laws protect individuals from health insurance discrimination based on genetic information. Genetic counselors are available through Saint Luke's Cancer Institute (SLCI) and can assist with insurance preauthorization after initial consultation. SLCI genetic counselors can be reached at 816-932-3300.

When to Order a PSA Screen Versus a PSA Diagnostic Test

Laboratory tests used for screening purposes are generally not covered by Medicare in the absence of symptoms or personal history of disease except as authorized by the Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report.

Medicare allows for a Prostate Specific Antigen (PSA) blood test to be performed for screening purposes once a year on men who are 50 and older. When a Prostate Specific Antigen (PSA) test is requested as part of a yearly routine exam in the absence of symptoms, a PSA SCREEN is ordered. Saint Luke's Regional Laboratories (SLRL) submits the appropriate ICD-9-CM screening code and the Advanced Beneficiary Notice (ABN) provided by the physician to Medicare.

A diagnostic Prostate Specific Antigen blood test (PSA DIAG) is ordered when the ICD-9 code submitted is covered by the Medicare Program, when testing is being performed to confirm or rule out a suspected diagnosis, or when there is an established diagnosis of disease.

Commercial insurance payers do not require Prostate Specific Antigen (PSA) testing performed for screening purposes to be submitted differently than diagnostic testing. A diagnostic Prostate Specific Antigen blood test (PSA DIAG) is ordered for patients who have commercial insurance payers. It is important to remember that both the orderable PSA Screen and PSA Diagnostic tests are performed utilizing the same laboratory test assay and reference ranges. They are the same laboratory test. Choosing the correct orderable test

enables SLRL to submit the patient account to Medicare or to the commercial insurance payer for processing using the established ICD-9 code and billing requirements.

New Specimen Label Policy

Starting this last June, the College of American Pathologists (CAP), one of the primary accrediting agencies for laboratories, implemented a new requirement for specimen containers being received into the laboratory. Containers such as tubes, cups and swabs are now required to be labeled with two patient identifiers.

Acceptable identifiers are:

- Patient Name
- Date of Birth
- Social Security Number
- Sticker (L#) from the Saint Luke's Test Requisition

Proper specimen labeling and identification is an issue which effects patient safety. Please use the additional identifier that works best for your system.

Oxcarbazepine Therapeutic Monitoring

Oxcarbazepine (Trileptal) has been FDA approved as monotherapy or adjuvant therapy for treating partial-onset and generalized tonic-clonic seizures in adults and children older than 6 years. It also has mood stabilizing properties and is prescribed for treatment of bipolar disorders. Oxcarbazepine is less toxic than carbamazepine.

Oxcarbazepine is a prodrug, which is metabolized in the liver to form 10-hydroxycarbamazepine (MHD). MHD is the pharmacologically active compound that accumulates in plasma. Peak concentration is reached 5.5 +/-2.3 hours after dosing. The circulating half life is 8-12 hours.

Therapeutic drug monitoring can be helpful in establishing an individual's optimal plasma concentration for controlling seizures without toxicity.

The therapeutic range is:

- Trough 6-10 ug/mL
- Peak >40 ug/mL

Specimen requirement is one green top or red top tube of blood.