**Direct-to-Consumer BRCA 1 and BRCA 2 Testing**

Ob-Gyn Risk Alliance® (OBRA) has received a number of questions from our insureds about the FDA advisories and Direct-to-Consumer (DTC) genetic tests. As a specialty liability insurance company, it is not our practice to give clinical advice. We do, however, want to be sure our insureds are aware of potential areas of risk in their practice. This toolkit has been exclusively developed by OBRA Risk Resource Advisors to address this need.

When patients provide DTC genetic test results to physicians and other health care providers, it is important to properly document in the medical record that the patient was referred to a genetic counselor. Should you receive a patient’s genetic test results that were ordered by another physician or provider, ensure the medical record reflects a thorough patient and family medical history, identification of known risk factors, appropriate diagnostic tests and referrals provided, and ongoing care management. Additionally, make sure the medical record reflects the patient education you provided and that patient questions were addressed.

In April 2017, The Food and Drug Administration (FDA) approved the first genetic health risk direct-to-consumer (DTC) genetic tests to 23andMe®, Inc. The approval was to test for 10 specific medical diseases/conditions. By providing 23 and Me a salvia sample, consumers receive information regarding their genetic health risk for developing these specific diseases/conditions. Subsequently, The American College of Obstetrics and Gynecology (ACOG) issued Committee Opinion Number 724 in November 2017 entitled, *Consumer Testing for Disease Risk*.

In March 2018, the FDA approved 23and Me for the first DTC BRCA 1 and BRCA 2 (selected variants) gene mutation test to identify certain consumers who are at an increased health risk for developing certain types of breast and ovarian cancer. Per the FDA’s March 6, 2018 press release: “This test provides information to certain individuals who may be at increased breast, ovarian or prostate cancer risk and who might not otherwise get genetic screening, and is a step forward in the availability of DTC genetic tests…While the detection of a BRCA mutation on this test does indicate an increased risk, only a small percentage of Americans carry one of these three mutations and most BRCA mutations that increase an individual’s risk are not detected by this test.”

ACOG has responded to the FDA’s DTC BRCA 1 and BRCA 2 test announcement with ACOG’s March 13, 2018 media release: “Direct to Consumer Genetic Testing for Breast and Ovarian Cancer Risk Creates Confusion”followed by their May 8 practice advisory“Response to FDA’s Authorization of BRCA1 and BRCA2 Gene Mutation Direct-to-Consumer Testing.” ACOG provides the following advice:

* Discourage patients from DTC testing
* Insufficient data may be provided. The BRCA 1 and 2 DTC only addresses 3 specific BRCA gene mutations
* Potential harm of misinterpreted test results
* Lack of reassurance associated with “negative” and “positive” test results
* Testing in absence of appropriate pre and post-testing counseling may prove harmful to patients and family members
* Possibility of “cascade” testing for the patient and blood relatives
* Genetic testing is complex and should be provided under the care of a provider with experience and expertise in cancer genetics
* Concerns over the management of confidential healthcare information

**References**:

* <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551185.htm>
* <https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests>
* <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Genetics/Consumer-Testing-for-Disease-Risk>
* <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm599560.htm>
* [Direct to Consumer Genetic Testing for Breast and Ovarian Cancer Risk Created Confusion](https://www.acog.org/About-ACOG/News-Room/Statements/2018/Direct-to-Consumer-Genetic-Testing-for-Breast-and-Ovarian-Cancer)
* <https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Practice-Advisory-Response-to-FDAs-Authorization-of-BRCA1-and-BRCA2-Genes-Direct-to-Consumer-Testing>
* <https://www.prnewswire.com/news-releases/acmg-responds-to-fdas-approval-for-direct-to-consumer-testing-for-three-brca-gene-mutations-300610375.html>