



**For Provider Information Only.
Do Not Submit with Pre-Authorization Request.**

**Genetic Testing Elements of Informed Consent
2019**

- **Basic Elements of Informed Consent for Genetic Testing (All elements required)**
 - Clarification of the patient's increased risk status
 - Explanation of how genetics affect cancer susceptibility
 - Potential benefits, risks and limitations of testing
 - Possible outcomes of testing (that is, positive, negative or uncertain test results)
 - Limited data regarding efficacy of methods for early detection and prevention
 - Possible psychological and social impact of testing
 - Counseling regarding therapeutic options, including limitation

- **Basic Elements of Informed Consent for Cancer Susceptibility (All elements required)**
 - Information on the specific testing being performed
 - Implications of a positive and negative result
 - Possibility that the test will not be informative
 - Options for risk estimation without genetic testing
 - Risk of passing a mutation to children
 - Technical accuracy of the test
 - Fees involved in testing and counseling
 - Psychological implications of test results (benefits and risks)
 - Risks of insurance or employer discrimination
 - Confidentiality issues
 - Options and limitations of medical surveillance and strategies for prevention following testing
 - Importance of sharing genetic test results with at-risk relatives so that they may benefit from the information