SCOPE:
The purpose of this policy is to define the process utilized for medical necessity review for use of genetic testing for cancer susceptibility risk.

DEFINITIONS AND ACRONYMS:
- American Cancer Society (ACS)
- American Society of Clinical Oncology (ASCO)

POLICY:
Genetic testing for an individual’s risk of developing a malignancy is the focus of this policy. Cancer susceptibility testing is predictive of future risk. 5-10% of all malignancies have a genetic component.

Typically, an individual is asymptomatic with a strong family history for malignancy.

A significant limitation to this type testing is lack of specificity in interpreting results. Weakly positive results often do NOT accurately predict future disease. It is important that positive tests have strong correlation with the development of future disease. Under such circumstances, medical management of individuals would expect to be modified accordingly.

A. Medical Necessity is present when ALL criteria are present
   1) The genetic condition is associated with a significant malignancy
   2) No other means of identification is available
   3) A specific mutation is identifiable from the medical literature
   4) Positive results will affect medical management
   5) Genetic counseling/education is complete

B. Absence of Medical Necessity exists when
   1) Multigene panels created by next generation sequencing are requested. Such testing provides information of uncertain significance, reduced accuracy & increased error rates. ACSO in 2015 based on peer-reviewed literature discouraged the use of the panels.
REFERENCES:


RELATED DOCUMENTS:

None

Nancy Horstmann
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REVISION HISTORY:

<table>
<thead>
<tr>
<th>Revision</th>
<th>Date</th>
<th>Description of Change</th>
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<tbody>
<tr>
<td>New</td>
<td>03/08/2018</td>
<td>Initial release.</td>
<td>Executive Leadership</td>
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<tr>
<td>A</td>
<td>04/24/2019</td>
<td>Annual review. Product lines updated.</td>
<td>Executive Leadership</td>
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<tr>
<td>B</td>
<td>05/18/2020</td>
<td>Annual review. Made minor grammar correction. No change to policy content.</td>
<td>Executive Leadership</td>
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