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THE AMERICAN SOCIETY OF BREAST SURGEONS

ORLANDO
19th Annual Meeting
GRANDE LAKES | May 2-6, 2018
Medicare patients who do not meet criteria for *BRCA1/2* genetic testing have similar rates of clinically actionable findings as those who do meet criteria.

All authors are employees and shareholders of Invitae Corporation.
>275,000 Americans are diagnosed with breast or ovarian cancer each year

~5-10% of breast and ovarian cancers are hereditary

Medicare covers 44 million lives in the US

Medicare subscribers often have limited income

Medicare criteria:
- are derived from the NCCN criteria
- reflect a high-penetrant phenotype
- require a personal diagnosis of cancer
Methods

- Prospective, consecutive series of Medicare patients
- Inclusion criteria:
  - Ordering indication of personal and/or family history of breast and/or gynecological cancer
  - Test included *BRCA1* and *BRCA2*
- Exclusion criteria:
  - Known P/LP variant in the family
  - Self-pay
- Ordering provider indicated if patient met testing criteria
  - Modified NCCN (more inclusive than Medicare)
  - Required personal diagnosis of relevant cancer
4,196 unique patients with Medicare
- 3,549 (85%) were in-criteria
- 647 (15%) were out-of-criteria

<table>
<thead>
<tr>
<th>Test result</th>
<th>In-criteria BRCA1/2 only</th>
<th>Out-of-criteria BRCA1/2 only</th>
<th>In-criteria large HBOC panel</th>
<th>Out-of-criteria large HBOC panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>3.2%</td>
<td>1.9%</td>
<td>10.5%*</td>
<td>9.0%*</td>
</tr>
<tr>
<td>Negative</td>
<td>96.8%</td>
<td>98.1%</td>
<td>89.5%</td>
<td>91.0%</td>
</tr>
</tbody>
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*p=0.26
in-criteria vs out-of-criteria
Conclusions & implications

• Medicare patients who do not meet current testing criteria have equal rates of actionable variants

• Current testing criteria are based on historically severe clinical presentations of high-penetrant genes/variants

• Broadening testing criteria is anticipated to capture more at-risk individuals and families
  – Incorporate moderate-penetrant phenotype
  – Include unaffected individuals