ASCO® Guidelines

SSO SOCIETY OF SURGICAL ONCOLOGY

Germline Testing in Patients with Breast Cancer: ASCO-SSO Guideline			
Clinical Question	**Recommendation**	**Type**	**Agreement**
Should clinicians offer *BRCA1/2* testing to all patients with newly diagnosed breast cancer?	**1.1.** All patients newly diagnosed with breast cancer with stage I-III or de novo stage IV/metastatic disease who are 65 years of age or younger at diagnosis should be offered *BRCA1/2* testing.	FC	87.50%
	1.2. All patients newly diagnosed with breast cancer with stage I-III or de novo stage IV/metastatic disease who are older than age 65 should be offered *BRCA1/2* testing if: • they are candidates for PARP inhibitor therapy for early-stage or metastatic disease, • they have triple-negative breast cancer, • their personal or family history suggests the possibility of a pathogenic variant, • they were assigned male sex at birth, • they are of Ashkenazi Jewish ancestry or are members of a population with an increased prevalence of founder mutations.	FC	92.50%
	1.3. Patients undergoing *BRCA1/2* testing should also be offered testing for other cancer predisposition genes as suggested by their personal or family history. Consultation with a provider experienced in clinical cancer genetics can help guide this decision-making and should be made available to patients when possible**.**	FC	90.00%
Should all people with recurrent disease, local or metastatic, or with second breast primary, be offered *BRCA1/2* testing?	**2.1.** All patients with recurrent breast cancer (local or metastatic) who are candidates for PARP inhibitor therapy should be offered *BRCA1/2* testing regardless of family history.	FC	97.50%
	Qualifying statement: Small single-arm studies show that oral PARP inhibitor therapy demonstrates high response rates in women with metastatic breast cancer and germline pathogenic variants in *PALB2*.		
	2.2. *BRCA1/2* testing should be offered to patients with a second primary cancer either in the contralateral or ipsilateral breast.	FC	89.74%
Should people with a personal history of breast cancer	**3.1.** All patients with a personal history of breast cancer diagnosed at 65 years or younger who are without active disease should be offered *BRCA1/2* testing if the result will inform personal risk management or family risk assessment.	FC	90.00%

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(and no active disease) be offered *BRCA1/2* testing?	**3.2.** All patients with a personal history of breast cancer diagnosed over age 65 with no active disease, who meet one of the following criteria, should be offered *BRCA1/2* testing if the result will inform personal risk management or family risk assessment: • their personal or family history suggests the possibility of a pathogenic variant, • they were assigned male sex at birth, • they had triple-negative breast cancer, • they are of Ashkenazi Jewish ancestry or are members of a population with an increased prevalence of founder mutations.	FC	94.87%
What is the value of testing patients with a diagnosis of breast cancer for breast cancer predisposition genes other than *BRCA1/2*?	**4.1.** Testing for high penetrance genes beyond *BRCA1/2*, including *PALB2*, *TP53*, *PTEN*, *STK11*, and *CDH1*, could inform medical therapy, influence surgical decision making, refine estimates of risks of second primary cancer, and inform family risk assessment, and thus should be offered to appropriate patients.	FC	92.31%
	4.2. Testing for moderate penetrance breast cancer genes currently offers no benefits for treatment of the index breast cancer but may inform risks of second primary cancer or family risk assessment, and thus may be offered to appropriate patients who are undergoing *BRCA1/2* testing.	FC	87.50%
	4.3. If a multi-gene panel is ordered, the specific panel chosen should take into account the patient's personal and family history. Consultation with a provider experienced in clinical cancer genetics can be helpful in selecting a specific multi-gene panel or interpreting its results and should be made available to patients when possible.	FC	91.43%
How should patients with breast cancer considering genetic testing be counseled?	**5.1.** Patients undergoing genetic testing should be given sufficient information before testing to provide informed consent.	FC	94.87%
	5.2. Patients with pathogenic variants should be provided with individualized post-test genetic counseling and offered referral to a provider experienced in clinical cancer genetics.	FC	95.00%
	5.3. Variants of uncertain significance should not alter management. Patients should be made aware that variants of uncertain significance may be reclassified as being pathogenic, and they should understand that periodic follow up is necessary. Consultation with a provider experienced in clinical cancer genetics can be helpful and should be made available to patients when possible.	FC	88.57%
	5.4. Patients without a pathogenic variant on genetic testing may still benefit from counseling, if there is a significant family history of cancer, and referral to a provider experienced in clinical cancer genetics is recommended.	FC	90.00%

Abbreviations. ASCO, American Society of Clinical Oncology; FC, formal consensus; PARP, poly(ADP-ribose) polymerase; SSO, Society of Surgical Oncology