

Practical Management Pearls for Immunotherapy for the Treatment of Breast Cancer

November 17, 2021

11:30 a.m. – 12:30 p.m. EST

Webinar Faculty



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Learning Objectives

- Describe breast cancer-specific considerations for selection and implementation of immune checkpoint inhibitors for metastatic triple-negative breast cancer
- Appropriately implement immune checkpoint inhibitors into treatment plans for early-stage triple-negative breast cancer
- Describe appropriate biomarker testing and specimen considerations for immunotherapy for triple-negative breast cancer

Webinar Outline

- Guideline development
- Advanced TNBC management
- Biomarker testing for mTNBC
- Resectable TNBC management
- Patient education and QOL

Development of the Guideline

Open access

Position article and guidelines

 Journal for
ImmunoTherapy of Cancer

Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of breast cancer

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Development of the Guideline

- Developed according to the Institute of Medicine's Standards for Developing Trustworthy Clinical Practice Guidelines
- Panel consisted of 17 experts in the field
- Recommendations are based upon published literature evidence, or clinical evidence where appropriate
- Consensus was defined at 75% approval among voting members

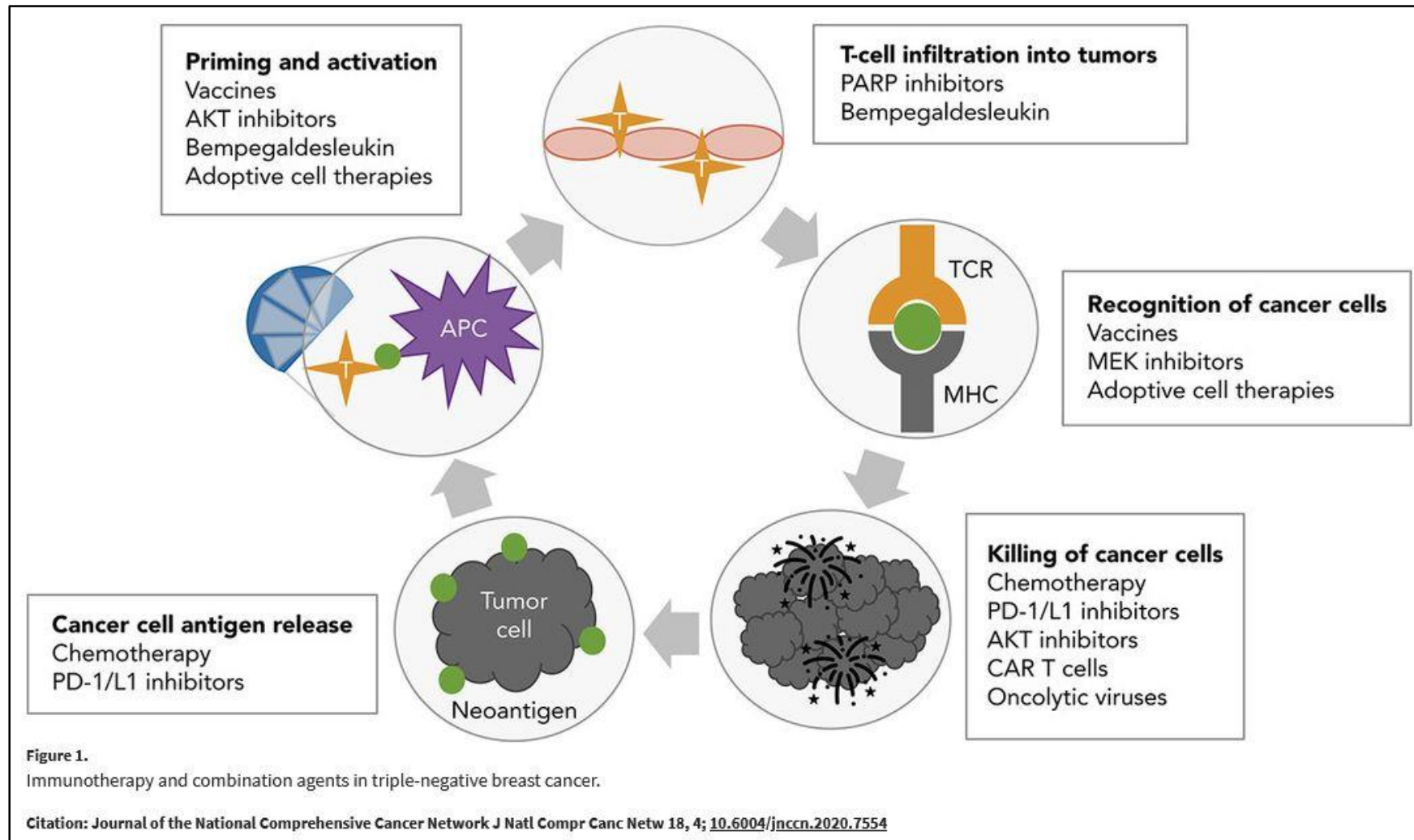
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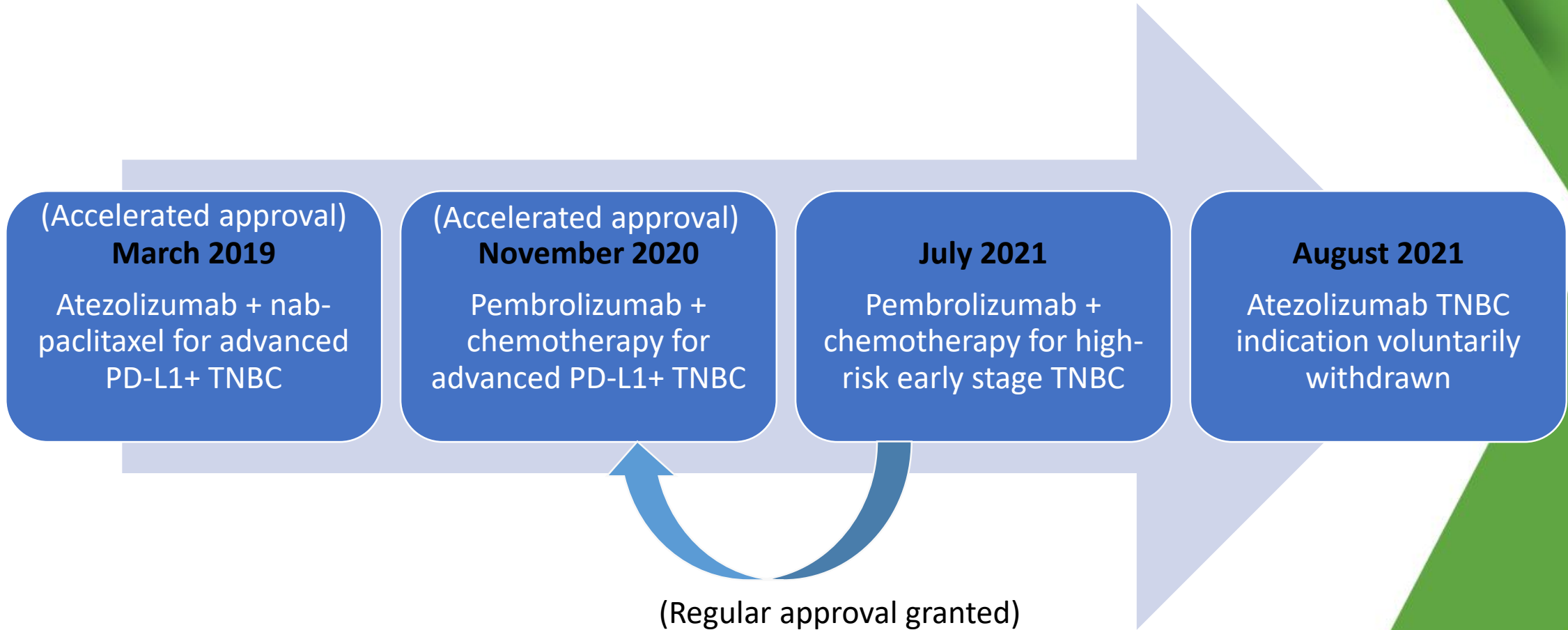
Expert Panel Recommendations on anti-PD-(L)1 ICI for Advanced TNBC

- Clinical trial enrollment remains a priority to further understand the benefit of checkpoint inhibition in metastatic breast cancer
- For patients with locally advanced/metastatic TNBC and PD-L1+ tumors by CPS score ≥ 10 using the 22C3 assay, pembrolizumab plus nab-paclitaxel, paclitaxel, or carboplatin and gemcitabine is recommended as one immunotherapy option for first-line treatment (LE:2), based on clinically meaningful PFS and OS improvement in KEYNOTE-355
- For patients with locally advanced/metastatic TNBC, pembrolizumab should only be added to chemotherapy (nab-paclitaxel, paclitaxel or carboplatin/gemcitabine combination) if tumors express PD-L1 with CPS ≥ 10 by the 22C3 assay (until PD-L1 assays are harmonized) (LE: 2)
- For patients with locally advanced/metastatic TNBC and PD-L1+ tumors being treated with atezolizumab, nab-paclitaxel is the only chemotherapy backbone that has demonstrated activity in randomized clinical trials (LE: 2). The indication for atezolizumab in this setting was voluntarily withdrawn in 2021.

Rationale for Combination Immunotherapy Approaches in TNBC



Timeline of ICI Approvals and Withdrawals for TNBC



Practical Pearls on ICI Therapy for Advanced-stage Breast Cancer

Data from Phase III Trials of ICIs for Advanced TNBC

Table 2 Trials of ICIs for recurrent/metastatic breast cancer and tissue-agnostic indications				
Trial name	Phase	Setting	Control and immunotherapy arms	Key outcome measures for FDA approval
Trials leading to FDA approvals				
IMpassion130	III	Previously untreated TNBC	Control (n=451): Placebo+nab-paclitaxel	PD-L1 IC+ PFS 7.5 vs 5 months HR 0.62 (95% CI 0.49 to 0.78; p<0.001)
			Immunotherapy (n=451): Atezolizumab+nab-paclitaxel	ITT PFS 7.2 vs 5.5 months HR 0.80 (95% CI 0.69 to 0.92; p=0.002)
KEYNOTE-355	III	Previously untreated TNBC	Control (n=281): Placebo+investigator's choice: nab-paclitaxel, paclitaxel, or gemcitabine+ carboplatin	CPS≥10 PFS 9.7 vs 5.6 months HR 0.65 (95% CI 0.49 to 0.86; p=0.0012)
			Immunotherapy (n=566): Pembrolizumab+investigator's choice: nab-paclitaxel, paclitaxel, or gemcitabine+ carboplatin	CPS≥1 PFS 7.6 vs 5.6 months HR 0.74 (95% CI 0.61 to 0.90; p=0.0014)

Data from Phase III Trials of ICI for Advanced TNBC

Hypothesis-generating trials				
KEYNOTE-119	III	TNBC that has progressed on prior therapy	Control (n=310): Investigator's choice: capecitabine, eribulin, gemcitabine, or vinorelbine	CPS\geq10 OS 12.7 vs 11.6 months HR 0.78 (95% CI 0.57 to 1.06; p=0.0574) CPS\geq1 OS 10.7 vs 10.2 months HR 0.86 (95% CI 0.69 to 1.06; p=0.0728) ITT OS 9.9 vs 10.8 months HR 0.97 (95% CI 0.82 to 1.15)
IMpassion131	III	Previously untreated TNBC	Control (n=220): Placebo+paclitaxel	PD-L1 IC+ PFS 6 vs 5.7 months HR 0.82 (p=0.20) ITT OS 19.2 vs 22.8 months HR 1.11
			Immunotherapy (n=431): Atezolizumab+paclitaxel	

ICI therapy in TMB-high solid tumors

Trials Leading to Tissue-agnostic Approvals of ICI

Trials leading to tissue-agnostic approvals				
Pooled analysis: KEYNOTE-016 KEYNOTE-164 KEYNOTE-012 KEYNOTE-028 KEYNOTE-158	Multi-cohort, single-arm	MSI-H or dMMR tumors that have progressed on prior therapy	Immunotherapy (n=149; five patients with breast cancer): Pembrolizumab	ORR 39.6% (95% CI 31.7% to 47.9%) CR rate 7% DOR 1.6+ to 22.7+months (78% lasting ≥6 months)
KEYNOTE-158	Multi-cohort, single-arm	TMB-H tumors (≥10 mut/Mb) that have progressed on prior therapy	Immunotherapy (n=102; 0 patients with breast cancer): Pembrolizumab	ORR 29% (95% CI 21% to 39%) CR rate 4% Median DOR not reached (57% lasting ≥12 months; 50% lasting ≥24 months)

Association between TMB and Benefit with ICI in TNBC

Trial	Agent(s) investigated	Number of patients evaluated for TMB (n TMB-H)	Outcomes: ORR; PFS HR (immunotherapy vs chemo); OS (immunotherapy vs chemo)		
KEYNOTE-119	Pembrolizumab vs chemotherapy (investigator's choice: capecitabine, eribulin, gemcitabine, or vinorelbine)	132 in pembrolizumab arm (n=12 TMB-H); 121 (n=14 TMB-H) in chemotherapy arm	TMB>10mut/Mb ORR 14.3% (95% CI 4% to 39.9%) vs 12.7% (95% CI 7.9% to 19.9%) PFS HR 1.14 (95% CI 0.42 to 3.07) OS HR 0.58 (95% CI 0.21 to 1.57)	TMB<10mut/Mb ORR 8.3% (95% CI 0.4% to 35.4%) vs 12.8% (95% CI 7.8% to 20.4%) PFS HR 1.24 (95% CI 0.92 to 1.67) OS HR 0.81 (95% CI 0.61 to 1.07)	
Trial	Agents investigated	Biomarker evaluable population (median TMB 4.38 mut/Mb)	OS HR by TMB quartile, PD-L1 positive population (HR (95% CI))		
			Quartile 1 (TMB 2.63 mut/Mb)	Quartile 2 (TMB 4.39 mut/Mb)	Quartile 3 (TMB 7.02 mut/Mb)
IMpassion130	Atezolizumab+chemotherapy vs placebo+chemotherapy	579 patients	0.69 (0.49 to 0.98)	0.59 (0.37 to 0.92)	0.37 (0.15 to 0.90)

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Biomarker Testing for Immunotherapy in Advanced/Metastatic TNBC

- PD-L1
- Tumor mutation burden (TMB)
- Microsatellite instability (MSI)/mismatch repair deficiency (dMMR)

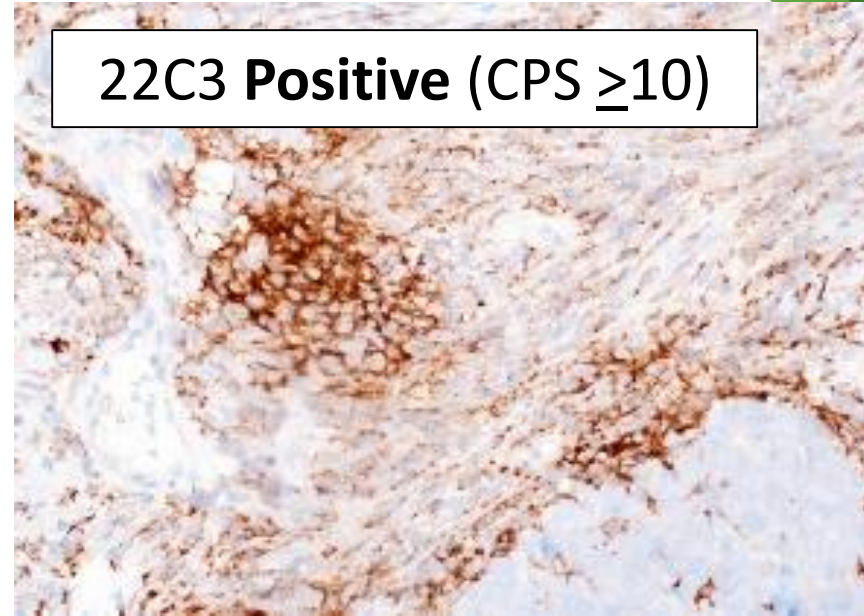
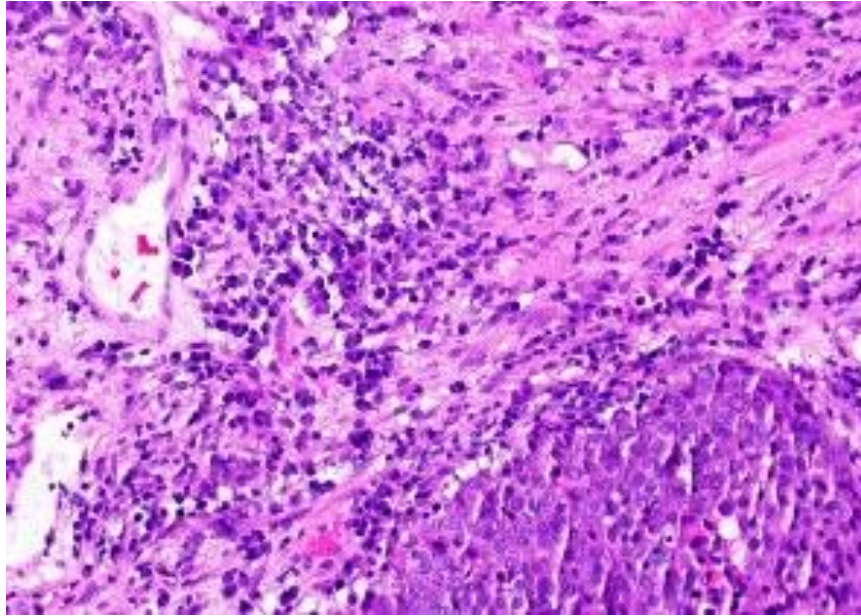
PD-L1 in Advanced/Metastatic TNBC

- KEYNOTE-355: the addition of pembrolizumab to chemotherapy improved PFS and OS in patients with PD-L1⁺ TNBC
- PD-L1 positivity by immunohistochemistry (IHC) is defined as a combined positive score (CPS) ≥ 10 , using an FDA-approved assay
- $$\text{CPS} = \frac{\text{number of PD-L1}^+ \text{ tumor cells} + \text{number of PD-L1}^+ \text{ immune cells}^a}{\text{total number of tumor cells}} \times 100$$
- Assay: PD-L1 IHC 22C3 pharmDx assay (“22C3 assay”)

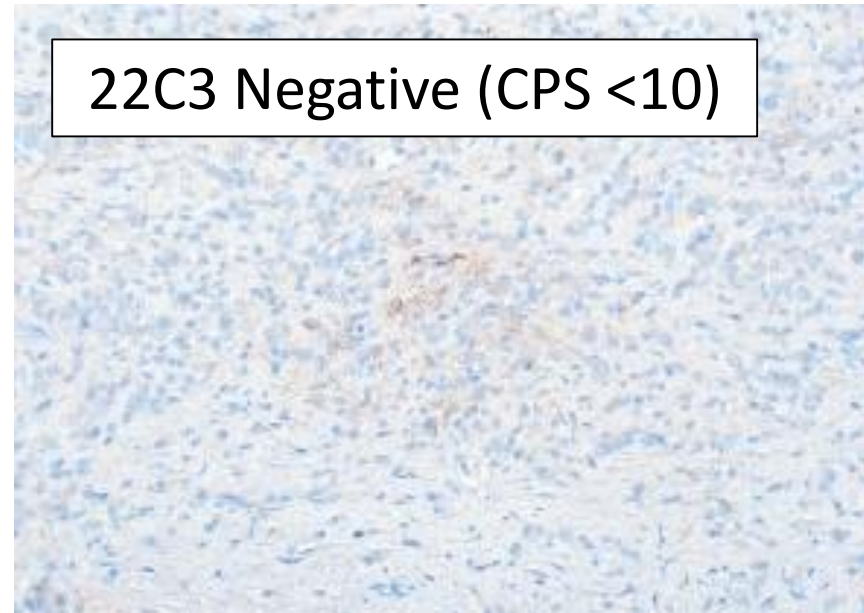
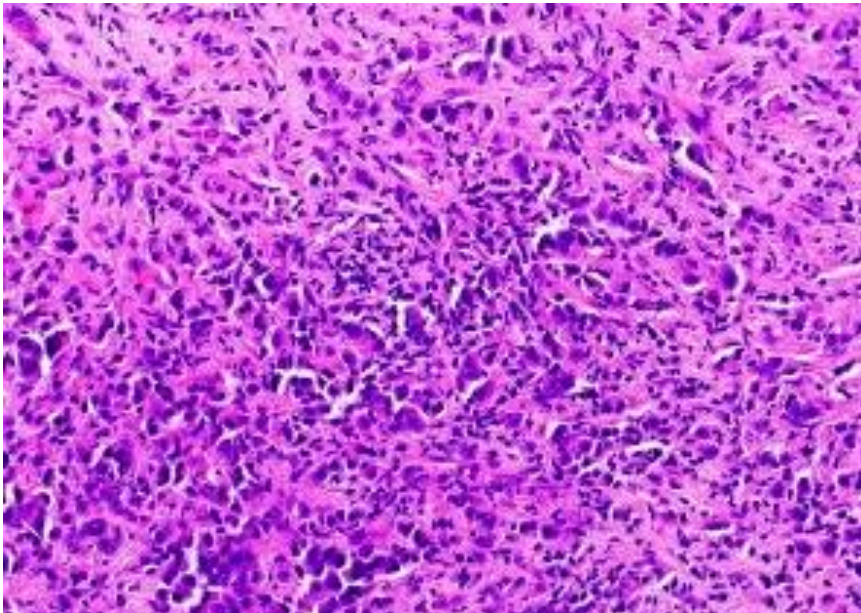
^a lymphocytes and plasma cells, located in tumor-associated stroma

PD-L1 IHC with the 22C3 assay

Locally
advanced
TNBC



Metastatic
TNBC to
chest wall



A Word on Atezolizumab and the SP142 assay in advanced/metastatic TNBC

- IMpassion130: the addition of atezolizumab to nab-paclitaxel improved outcomes in patients with PD-L1⁺ TNBC
- Indication was voluntarily withdrawn in 2021
- PD-L1 positivity by (IHC) is defined as an immune cell (IC) score ≥ 1
- IC score = percent of tumor area occupied by PD-L1⁺ immune cells^a
- Assay: Ventana PD-L1 (SP142) assay (“SP142 assay”)

^a lymphocytes, plasma cells, macrophages, and neutrophils, in tumor-associated stroma

PD-L1 IHC Assays

Table 5 Summary of anti-PD-L1 antibodies and companion assays					
Antibody clone	Assay	Platform	PD-L1 scoring for breast cancer	Companion diagnostic status	Companion diagnostic approval for TNBC
SP142	VENTANA PD-L1 (SP142)	VENTANA	IC score=the percentage of the tumor area containing ICs labeling with PD-L1 at any intensity above background	Yes No	IC score $\geq 1\%$ indicates eligibility for atezolizumab (+nab-paclitaxel)
22C3	PD-L1 IHC 22C3 pharmDx	Dako	CPS=number of PD-L1 staining cells (including TCs, lymphocytes, and macrophages), divided by the total number of viable TCs, multiplied by 100	Yes	CPS ≥ 10 indicates eligibility for pembrolizumab (+chemotherapy)
28-8	PD-L1 IHC 28-8 pharmDx	Dako	Not applicable	No	None
SP263	VENTANA PD-L1 (SP263)	VENTANA	Not applicable	Not for breast cancer	None
CPS, combined positive score; IC, immune cell; IHC, immunohistochemistry; PD-L1, programmed death-ligand 1; TC, tumor cell; TNBC, triple-negative breast cancer.					

Specimen Considerations for PD-L1 Biomarker Testing

Expert Panel recommendations:

- Although PD-L1 testing of primary lesions may not correlate with expression in metastatic disease, benefit was observed in IMpassion130 with any PD-L1+ result regardless of whether primary or metastatic tumor. **PD-L1 testing should be performed on the metastatic tumor, if available, but testing on primary tumor is acceptable** (LE: 2).
- When considering metastatic sites to test for PD-L1, it is preferable to prioritize extrahepatic^a sites or the primary tumor, if available
- PD-L1 testing should not be performed on fine needle aspirated cell-block specimens or decalcified bone

^a metastases to the liver are often non-inflamed

Measures of Genomic Instability in Advanced/Metastatic TNBC

- Tumor mutation burden (TMB)-high^a status

~5% breast cancers

Result of genomic instability

- Microsatellite instability (MSI)-high status

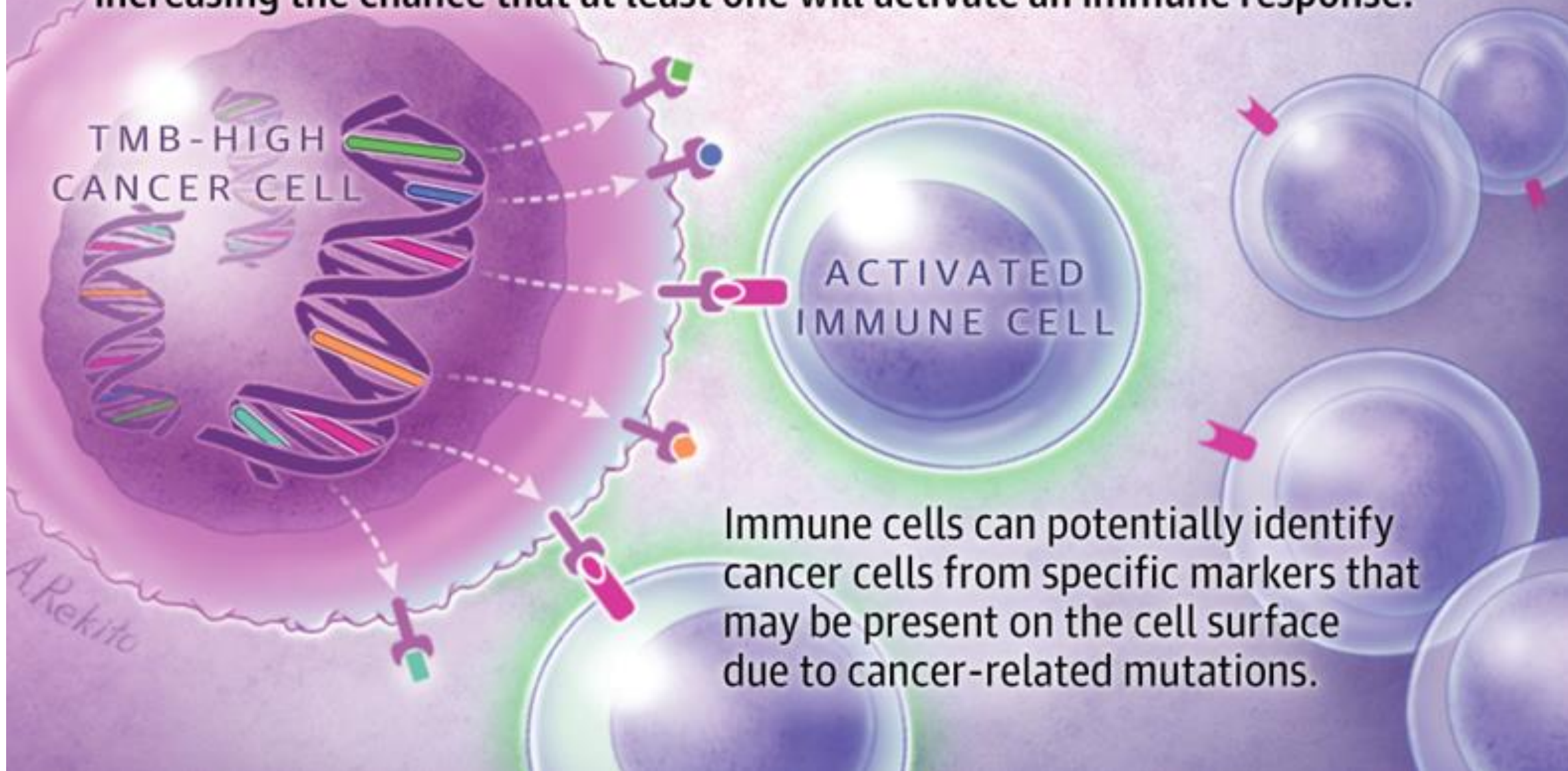
~2% breast cancers

- Mismatch repair protein deficiency (dMMR)

Causes of genomic instability

^a TMB-high ≥ 10 mutations per megabase

Cancers with high tumor mutation burden (TMB-high) have more mutations, increasing the chance that at least one will activate an immune response.



Immune Checkpoint Inhibition for TMB-high, MSI-high, and dMMR Solid Tumors

- Single-agent pembrolizumab is approved for patients with TMB-high, MSI-high or dMMR advanced solid tumors, irrespective of histology
- First *tumor agnostic* approval of immunotherapy (ie, approval for advanced solid tumors of any primary site)
- TMB is included in most next-generation sequencing assays used to evaluate the presence of actionable mutations
- MSI is determined by PCR
- dMMR is determined by mismatch repair protein IHC

Expert Panel Recommendations on Biomarker Testing for Advanced TNBC

- All patients with unresectable locally advanced or metastatic TNBC should have tumor tissue tested for PD-L1 by an FDA-approved assay for breast cancer
- All patients who are candidates for immunotherapy treatment for metastatic TNBC should have tumor tissue tested for PD-L1 at least once, irrespective of line of therapy or prior immunotherapy in the adjuvant or neoadjuvant setting
- With the withdrawal of the indication for atezolizumab with nab-paclitaxel in metastatic TNBC, one companion diagnostic is approved by the FDA for PD-L1 testing in metastatic TNBC: the 22C3 assay with tumor and IC scoring by combined positive score. Benefit is seen for adding pembrolizumab to chemotherapy in patients with tumors expressing PD-L1 by CPS score ≥ 10 (LE: 2).
- Patients deriving clinical benefit from atezolizumab-based treatment in the absence of clinically significant toxicity or disease progression should continue on atezolizumab plus nab-paclitaxel rather than change therapy
- All patients with locally advanced or metastatic breast cancer should undergo comprehensive genomic profiling, including testing for TMB and MSI

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Expert Panel Recommendations on Immunotherapy for Early-stage TNBC

- For all patients with stage II and III TNBC, clinical trial enrollment should be considered if available
- For patients with high-risk early-stage TNBC, pembrolizumab in combination with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery is a standard of care based on statistically significant and clinically meaningful improvement in EFS in KEYNOTE-522. Overall survival (OS) data is still maturing (LE: 2).
- For patients with stage II and III TNBC and no available trial, the addition of atezolizumab to standard neoadjuvant chemotherapy may be considered, although not FDA-approved at the time of publication and the IMpassion031 trial was not powered to assess EFS (LE: 2)
- Based on accumulated data to date, immunotherapy regimens for stage II and III TNBC should at least include an anthracycline and a taxane with or without carboplatin (LE: 2)



Approved and Emerging Indications for anti-PD-(L)1 ICI in Early-stage Breast Cancer

Table 4 Completed phase II/III neoadjuvant immunotherapy trials for early-stage breast cancer

Trial name Trial identifier	Phase	Subtype	Control and immunotherapy arms	pCR rate (95% CI) (investigational vs control)
I-SPY 2* NCT01042379	II	HER2–	Control (n=201): paclitaxel × 4 → doxorubicin+cyclophosphamide × 4 → surgery	HR+/HER2– 30% (17% to 43%) vs 13% (7% to 19%)
			Investigational (n=69): paclitaxel+pembrolizumab × 4 → doxorubicin plus cyclophosphamide × 4 → surgery	TNBC 60% (44% to 75%) vs 22% (13% to 30%)
		HER2–	Control (n=295): paclitaxel × 4 → doxorubicin+cyclophosphamide × 4 → surgery	HR+/HER2– 15% (1% to 29%) vs 15% (9% to 20%)
			Investigational (n=73): paclitaxel+pembrolizumab × 4 → pembrolizumab × 4 → surgery	TNBC 27% (9% to 45%) vs 27% (19% to 35%)
		HER2–	Control (n=299): paclitaxel × 4 → doxorubicin+cyclophosphamide × 4 → surgery	HR+/HER2– 28% (18% to 38%) vs 14% (9% to 19%)
			Investigational (n=74): olaparib+durvalumab+paclitaxel × 4 → doxorubicin+cyclophosphamide × 4 → surgery	TNBC: 47% (29% to 64%) vs 27% (20% to 34%)

*pCR rate in I-SPY 2 trial is estimated due to adaptive clinical trial design.

EC, epirubicin/cyclophosphamide; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; ITT, intent-to-treat; LN, lymph node; NR, not reported; pCR, pathologic complete response; PD-L1, programmed death-ligand 1; TNBC, triple-negative breast cancer.

GeparNuevo NCT02685059	II	TNBC	Control (n=86): nab-paclitaxel × 4 →epirubicin+cyclophosphamide × 4 → surgery Investigational (n=88): nab-paclitaxel+durvalumab × 4 → EC+durvalumab × 4 → surgery	ITT 53.4% (42.5% to 61.4%) vs 44.2% (33.5% to 55.3%)
				Window cohort 61% (NR) vs 41.4% (NR)
KEYNOTE-522 NCT03036488	III	TNBC	Control (n=390): paclitaxel+carboplatin+placebo → doxorubicin+cyclophosphamide/ epirubicin+cyclophosphamide+placebo × 4 → surgery → placebo Investigational (n=784): paclitaxel+carboplatin+pembrolizumab → doxorubicin+cyclophosphamide/ epirubicin+cyclophosphamide+pembrolizumab × 4 → surgery → pembrolizumab	ITT 63% (59.5% to 66.4%) vs 55.6% (50.6% to 60.6%)
				PD-L1-positive 68.9% vs 54.9%
				PD-L1-negative 45.3% vs 30.3%
				LN-negative 64.9% (NR) vs 58.6% (NR)
				LN-positive 64.8% (NR) vs 44.1 (NR)

NeoTRIPaPDL1 NCT02620280	III	TNBC	Control (n=142): nab-paclitaxel+carboplatin × 8 → surgery → doxorubicin+cyclophosphamide/ epirubicin+cyclophosphamide/5 FU+epirubicin+cyclophosphamide × 4	ITT 43.5% (35.1% to 52.2%) vs 40.8% (32.7% to 49.4%)
			Investigational (n=138): nab-paclitaxel+carboplatin+atezoli- zumab × 8 → surgery → doxorubicin+cyclophosphamide/ epirubicin+cyclophosphamide/5 FU+epirubicin+cyclophosphamide × 4	PD-L1-negative 32.2% (NR) vs 32.3% (NR)
				PD-L1-positive 51.9% (NR) vs 48% (NR)
IMpassion031 NCT03197935	III	TNBC	Control (n=165): placebo × 6+nab-paclitaxel × 12 → placebo+doxorubicin+cyclophosphamide × 4 → surgery → monitoring	ITT 58% (50% to 65%) vs 41% (34% to 49%)
			Investigational (n=168): atezolizumab × 6+nab-paclitaxel × 12 → atezolizumab+doxorubicin+cyclophosphamide × 4 → surgery →atezolizumab	PD-L1-positive 69% (57% to 79%) vs 49% (38% to 61%)

Who Is a Good Candidate for Immunotherapy in the Early-stage Setting?

Expert Panel recommendations:

- For patients with stage II and III TNBC in KEYNOTE-522, patients continued immunotherapy from the neoadjuvant setting into the adjuvant setting. The potential benefits of adjuvant immunotherapy must be weighed against the potential for toxicities with treatment.
- For patients with early stage TNBC who receive pembrolizumab, serum cortisol should be tested at baseline, prior to surgery, and as clinically indicated

Biomarker Testing for Immunotherapy for Early-stage TNBC

Expert Panel recommendations:

- For patients with stage II and III TNBC, improved pCR rates with either neoadjuvant pembrolizumab or atezolizumab have been observed, regardless of PD-L1 status (LE: 2)
- PD-L1 testing is not recommended for patients with early-stage breast cancer at this time (LE: 2)
- Stromal TIL assessment in primary lesions is prognostic in early TNBC and HER2+ breast cancer (LE: 1), but has not been validated to direct clinical decision-making for chemotherapy or immunotherapy
- Biomarker assessment, including repeat receptor profiles (ER/PR/HER2) and PD-L1 status as well as NGS should be considered at first relapse (LE: 3)

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Major Toxicities Reported in ICI Trials for Breast Cancer

Table 7 Reported incidence of irAEs in published ICI clinical trials for metastatic TNBC (adapted from D'Abreo and Adams, *Nat Rev Clin Oncol*, 2019²¹⁴)

irAE		All grades (%)	Grade 3–4 (%)	Grade 5 (%)
Dermatologic	Pruritus, rash	18	0.5	0
Endocrine	Hypothyroidism	12	0	0
	Hyperthyroidism	5	0.1	0
Gastro-intestinal	Hepatitis, elevated transaminases	10	3	0.2
	Colitis, diarrhea	2.5	0.45	0
Hematologic	Prespecified autoimmune anemia, lymphopenia, thrombocytopenia and clotting abnormalities	4	1	0.2
Respiratory	Pneumonitis	3	0.5	0.1
Other (<1%)	Adrenal insufficiency, type 1 diabetes, ocular, myocarditis, neurological/meningitis, nephritis/ elevated creatinine	<1	<0.5	0

ICI, immune checkpoint inhibitor; irAEs, immune-related adverse events; TNBC, triple-negative breast cancer.

Toxicity Considerations for Early-stage versus Advanced TNBC

Expert Panel recommendations:

- Patients should be monitored for symptoms of immune toxicities during immunotherapy and for at least 12 months after discontinuation of treatment. Importantly, irAEs may occur after immunotherapy has been discontinued and other therapy initiated (LE: 1)
- For patients with breast cancer who experience irAEs during immunotherapy treatment, management should generally follow the most updated guidelines (eg, SITC, ASCO, National Comprehensive Cancer Network (NCCN)) as this field is rapidly evolving
- For patients with breast cancer who develop thyroid disorders or adrenal insufficiency while on treatment, immunotherapy can generally be continued (LE: 2)

Key Considerations for Patient Education

Expert Panel recommendations:

- For patients receiving immunotherapy, education should be provided, including the differences between chemotherapy and immunotherapy. Whenever possible, caregivers and family members should be included in these conversations.
- Patients and providers should be educated about potential irAEs, including the expected timing of symptom onset and management of toxicity with immunotherapies, rationale for holding doses as opposed to dose reductions, and detailed parameters for when to contact their care team
- For patients being treated with immunotherapy, education should include the importance of early recognition and management of irAEs, emphasizing that some of the more common toxicities have vague symptoms and therefore any change from baseline health should be reported. Additionally, patients should be encouraged to inform all their current and future healthcare providers that they have been treated with immunotherapy.
- Patients should be encouraged to use contraception while receiving immunotherapy, and a discussion about fertility should be initiated prior to treatment

Conclusions

- Checkpoint inhibition + chemotherapy is a standard therapy for patients with advanced PDL1+ TNBC
 - PDL1 testing with 22C3 using CPS \geq 10 as a cut-off is standard for selecting patients for therapy with pembrolizumab
- Preoperative chemotherapy + checkpoint inhibition is standard of care for patients with early stage 2/3 TNBC
 - PDL1 testing is not needed to select patients for checkpoint inhibition with early stage disease
- Patients with metastatic breast cancer and high TMB (\geq 10 mutations/MB) are candidates for pembrolizumab monotherapy
- Further work is ongoing looking at the utility of checkpoint inhibitors with other breast cancer subtypes

Learn more and register at:

<https://www.sitcancer.org/CPG-webinars>

Case Studies in Immunotherapy for the Treatment of Breast Cancer

December 1, 2021, 11:30 a.m. – 12:30 p.m. ET

Practical Management Pearls in Immunotherapy for the Treatment of Hepatocellular Carcinoma

December 6, 2021, 5:30 – 6:30 p.m. ET

Practical Management Pearls for Immunotherapy for the Treatment of Head and Neck Squamous Cell Carcinoma

December 9, 2021, 11 a.m. – 12 p.m. ET

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Eight online seminars will address key questions in the field of cancer immunotherapy **drug development**

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SEMINAR 8: T CELL SELECTION FOR ADOPTIVE CELL THERAPY

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A Focus on Gastrointestinal Cancers

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December 14, 2021, 12 – 4 p.m. ET

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