

## Patient Resource:

# Postsurgery Treatment Options for HER2-Negative Early-Stage Breast Cancer



The goal of this questionnaire is to give you more information about HER2-negative early-stage breast cancer and your treatment options after you've had surgery. (Treatment after surgery is called adjuvant therapy, and treatment before surgery is called neoadjuvant therapy.) When doctors recommend treatments, they look at many characteristics of the cancer to customize treatment as much as possible. Many of the questions below are about these cancer characteristics.

This questionnaire is designed to be used with **the interactive treatment tool**, which was developed in partnership with Clinical Care Options to help doctors select the best treatments for patients. You or your doctor may enter your responses to the questionnaire into this tool to see treatment recommendations from 5 medical experts. You can see how the experts responded to 5 sample case studies at the end of this document; the cases all describe HER2-negative early-stage breast cancer diagnoses, but their different characteristics led to different treatment recommendations.

Understanding your diagnosis and treatment options will make it easier to partner with your oncology care team to make decisions that work for you.

Before you begin, you'll want to have as much information about your diagnosis as possible. If you don't have all of the information listed below, ask your oncology care team to help you answer the questions.

## Treatment Decisions and Your Quality of Life:

### What Do You Need to Tell Your Doctor?

Information about the nature of the tumor isn't the only factor in making decisions about treatment. Treatments need to work for you and fit into your life—and your life priorities—as much as possible. It's important to think about what your preferences, needs, and priorities regarding treatment are and to share these with your care team.



To be as comfortable with your treatment as possible, you'll want to strike a balance between treatment priorities and your quality of life. At some points in your journey, you may choose to give more weight to treatment, even if it affects your quality of life. At other times, your quality of life may be your priority. Knowing what you value will help you find this balance.

It's important to think carefully about your expectations, desires, and hopes for treatment and about how it will affect your life—and then to discuss this with your doctor. Some questions you may want to ask yourself include:

- Are there events coming up that you don't want to miss or activities you don't want to give up? Will work or family situations make it difficult for you to go in for treatments regularly?
- How will you get to and from the clinic?
- Do you have a support system of family and friends? Will you need extra help at home while you're having treatments or if you don't feel well after having them?



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- Are there certain side effects that you're more willing or less willing to tolerate? For example, some people may be okay with feeling tired but never want to feel pain.
- Do you regularly spend time in another area—for example, as a “snowbird” who spends winters farther south—so that you will need treatment at both a home and an away location?
- Are you planning to move to a different region?
- Do you need help talking with loved ones?
- Are you concerned about costs?
- Do you have other worries or fears? What other concerns do you have?

Make notes as you think about it and keep them up to date as time goes by. If anything about your priorities or your situation changes, it's important to let your doctor know.

As you reflect on your own priorities and learn more about HER2-negative early-stage breast cancer, you'll become more confident in making decisions about your disease. Working together, you and your doctor can make sure your health and treatment are balanced with all the other parts of your life.

## Questionnaire:

### Adjuvant Therapy in HER2-Negative Early-Stage Breast Cancer Treatment

To prepare for your treatment, fill out this questionnaire as much as you can, based on your diagnosis, past treatments, and the test results you've received.

**If your answer to any question is “I don't know,” reach out to someone on your oncology care team to get the answer.**



This treatment decision support tool starts by assuming that you:

- Have been diagnosed with HER2-negative early-stage breast cancer
- Have undergone surgery
- Do not have any other health conditions or other traits that would affect the choice of treatment, besides those you describe when answering the tool's questions

#### 1. Which of the following best describes the cancer's hormone receptor (or HR) status?

- ☐ Hormone receptor negative (meaning triple-negative cancer [or TNBC])
- ☐ Hormone receptor positive
- ☐ I don't know

***If the cancer is hormone receptor negative (TNBC), please continue to questions 2-6. If the cancer is hormone receptor positive, please continue to questions 7-11.***

#### 2. Which of the following best describes the breast cancer?

- ☐ Tumors up to 2 centimeters in size and no cancer in any lymph nodes (node negative)
- ☐ Tumors larger than 2 centimeters and/or cancer in at least 1 lymph node (node positive)
- ☐ I don't know

**3. Which of the following presurgery (neoadjuvant) treatment regimens did you receive?**

- ☐ Chemotherapy plus pembrolizumab (together, this is known as the KEYNOTE-522 regimen)
- ☐ Chemotherapy only
- ☐ No neoadjuvant therapy
- ☐ I don't know

**4. Did you have a pathologic complete response (or pCR; no cancer cells detected after treatment)?**

- ☐ Yes
- ☐ No
- ☐ I don't know

**5. Have you tested positive for a *BRCA1* or *BRCA2* mutation, or both?**

- ☐ Yes
- ☐ No
- ☐ I don't know

**6. Do you fit the eligibility criteria for the TNBC group in the OlympiA trial? (See the callout)**

- ☐ Yes
- ☐ No
- ☐ I don't know

**To be eligible for the TNBC group in the OlympiA trial, you need to:**

- Be at least 18 years of age
- Test positive for a *BRCA1* or *BRCA2* mutation, or both
- Have HER2-negative primary breast cancer that is still at high risk for recurring after being treated with chemotherapy before or after surgery. TNBC is considered to be at a high risk for recurring if:
  - You had surgery followed by chemotherapy, and you either (a) have cancer in at least 1 axillary (armpit) lymph node (axillary node positive, or  $\geq$ pN1) with any tumor size, or (b) you do not have cancer in an axillary lymph node (axillary lymph node negative, or pN0) and you have an invasive primary tumor larger than 2 centimeters ( $\geq$ pT2)
  - You were previously treated with chemotherapy followed by surgery, and you did not experience a pathologic complete response (pCR, or no remaining signs of cancer)
- Have completed all treatments directed at the tumor itself, including surgery and radiation therapy, between 2 and 12 weeks before starting the trial
- Have completed 6 or more cycles of chemotherapy before or after surgery that included anthracyclines, taxanes, or both; this can include platinum chemotherapy

**The following questions are for cancers that are hormone receptor positive.**

**7. Has your doctor recommended that you receive adjuvant chemotherapy?**

- ☐ Yes
- ☐ No
- ☐ I don't know

**8. If so, what type of adjuvant endocrine therapy has your doctor recommended?**

- ☐ Aromatase inhibitor  $\pm$  ovarian function suppression
- ☐ Tamoxifen  $\pm$  ovarian function suppression
- ☐ I don't know

**9. Have you tested positive for a *BRCA1* or *BRCA2* mutation, or both?**

- ☐ Yes
- ☐ No
- ☐ I don't know

**10. Do you fit the eligibility criteria for the HR-positive/HER2-negative group in the OlympiA trial? (See the callout)**

- ☐ Yes
- ☐ No
- ☐ I don't know

**To be eligible for the HR-positive/HER2-negative group in the OlympiA trial, you need to:**

- Be at least 18 years of age
- Have tested positive for a *BRCA1* or *BRCA2* mutation, or both
- Have HR-positive/HER2-negative primary breast cancer that is still at high risk for recurring after being treated with chemotherapy before or after surgery. HR-positive/HER2-negative breast cancer is considered to be at a high risk for recurring if:
  - You were previously treated with surgery followed by chemotherapy, and cancer was detected in 4 or more lymph nodes
  - You previously received chemotherapy followed by surgery and you did not experience a pathologic complete response (pCR; no remaining signs of cancer) and have a CPS + EG score of 3 or higher. *Note: Doctors calculate the CPS + EG score using the cancer's stage, estrogen receptor status, and histologic grade (or how different a cancer cell's appearance and growth patterns are from normal, healthy breast cells)*
- Have completed all treatments directed at the tumor itself, including surgery and radiation therapy, between 2 and 12 weeks before starting the trial
- Completed 6 or more cycles of chemotherapy before or after surgery that included anthracyclines, taxanes, or both; this can include platinum chemotherapy
- Have been treated with adjuvant bisphosphonates and adjuvant endocrine therapy according to the guidelines at the facility where you were treated

**11. Do you fit the criteria set out by the FDA for receiving abemaciclib as adjuvant treatment of node-positive HR-positive/HER2-negative early-stage breast cancer that is considered at high risk of recurrence? (See the callout)**

- ☐ Yes
- ☐ No
- ☐ I don't know

**To be eligible to receive adjuvant treatment of node-positive HR-positive/HER2-negative early-stage breast cancer that is considered at high risk of recurrence, you need to have either:**

- Cancer in 4 or more axillary (armpit) lymph nodes
- Cancer in 1-3 axillary lymph nodes and either a tumor grade of 3 or a tumor size of 5 centimeters or larger

## Using Case Studies to Help With Decision-making

To see how breast cancer experts decide on treatments, we've included 5 example breast cancer patient cases below. The patients in all 5 cases:

1. Have HER2-negative early-stage breast cancer
2. Have had surgery to remove the cancer
3. Have no other health conditions or other traits that would affect the choice of treatment

Each case includes recommendations from 5 highly regarded breast cancer experts about what adjuvant therapy they think is best for patients in that situation.

For example, Case Scenario 1 describes someone who:

- Has HER2-negative breast cancer that is also negative for hormone receptors (estrogen and progesterone receptors)—this is often called “triple-negative breast cancer” (or TNBC)
- Has either a tumor larger than 2 centimeters or cancer in at least 1 lymph node
- Tested negative on genetic testing for *BRCA1* and *BRCA2* mutations
- Has had neoadjuvant treatment and surgery, meaning the patient was given a combination of drugs—a chemotherapy drug plus an immunotherapy called pembrolizumab—and then had surgery to remove the cancer and possibly some lymph nodes
- Still has some signs of cancer according to a pathology report after the surgery (this is known as having “no pathologic complete response,” or being non-pCR), which means the cancer is more likely to grow back

In that situation, all 5 experts recommended that the patient should next be given the combination of capecitabine, a chemotherapy medication, and pembrolizumab again as adjuvant treatment following surgery.

## The Experts

The experts providing recommendations were:

- **Laura Huppert, MD**, Assistant Professor of Medicine, Division of Hematology/Oncology, University of California, San Francisco
- **Kevin Kalinsky, MD, MS**, Division Director, Medical Oncology, and Professor, Department of Hematology and Medical Oncology, Winship Cancer Institute at Emory University
- **Reshma Mahtani, DO**, Chief of Breast Medical Oncology, Miami Cancer Center, Baptist Health South Florida
- **Laura Spring, MD**, Breast Medical Oncologist, Mass General Cancer Center, Harvard Medical School
- **Tiffany Traina, MD, FASCO**, Associate Attending, Breast Medicine Service, Vice Chair of the Department of Medicine, and Section Head of the TNBC Clinical Research Program at Memorial Sloan Kettering Cancer Center; Associate Professor of Medicine, Weill Cornell Medicine



## The Cases and Recommendations

### Early-Stage TNBC Cases

**Case Scenario 1: The experts recommend the following adjuvant therapy for a patient who:**

- Has early-stage TNBC
- Has a tumor larger than 2 centimeters and/or has node-positive disease (cancer in 1 or more lymph nodes)
- Received neoadjuvant chemotherapy plus pembrolizumab
- Did not have a pathologic complete response (has non-pCR status) as a result of that therapy
- Tested negative on genetic testing for germline *BRCA1* and *BRCA2* mutations

| Expert 1 Recommendation      | Expert 2 Recommendation      | Expert 3 Recommendation      | Expert 4 Recommendation      | Expert 5 Recommendation      |
|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| Capecitabine + pembrolizumab | Capecitabine + pembrolizumab | Capecitabine + pembrolizumab | Capecitabine + pembrolizumab | Capecitabine + pembrolizumab |

**Case Scenario 2: The experts recommend the following adjuvant therapy for a patient who:**

- Has early-stage TNBC
- Has a tumor larger than 2 centimeters and/or has node-positive disease (cancer in 1 or more lymph nodes)
- Did not receive any treatment before surgery
- Tested positive on genetic testing for a germline *BRCA1* or *BRCA2* mutation, or both

| Expert 1 Recommendation           | Expert 2 Recommendation           | Expert 3 Recommendation           | Expert 4 Recommendation           | Expert 5 Recommendation                                                                |
|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|----------------------------------------------------------------------------------------|
| Chemotherapy followed by olaparib | Chemotherapy followed by olaparib | Chemotherapy followed by olaparib | Chemotherapy followed by olaparib | Chemotherapy followed by olaparib<br><i>Comment: May consider adding pembrolizumab</i> |

**Additional Expert Comments:** For the chemotherapy regimen, experts recommend dose-dense AC/T (doxorubicin, cyclophosphamide, paclitaxel), with or without carboplatin.

### HR-Positive Early-Stage Breast Cancer Cases

**Case Scenario 3: The experts recommend the following adjuvant therapy for a patient who:**

- Has HR-positive early-stage breast cancer
- Has completed adjuvant chemotherapy
- Will receive adjuvant endocrine therapy with an aromatase inhibitor, along with an ovarian function suppressor for those who were assigned female at birth and have not been through menopause
- Tested negative for *BRCA1* or *BRCA2* mutations, or both

| Expert 1 Recommendation | Expert 2 Recommendation                                                             | Expert 3 Recommendation | Expert 4 Recommendation | Expert 5 Recommendation |
|-------------------------|-------------------------------------------------------------------------------------|-------------------------|-------------------------|-------------------------|
| Endocrine therapy only  | Endocrine therapy only<br><i>Comment: Add abemaciclib for node-positive disease</i> | Endocrine therapy only  | Endocrine therapy only  | Endocrine therapy only  |

**Case Scenario 4: The experts recommend the following adjuvant therapy for a patient who:**

- Has HR-positive early-stage breast cancer
- Has completed adjuvant chemotherapy
- Will receive adjuvant endocrine therapy with an aromatase inhibitor, along with an ovarian function suppressor for those who were assigned female at birth and have not been through menopause
- Is considered to have a high or very high risk of the cancer recurring
- Tested negative for *BRCA1* and *BRCA2* mutations
- Is eligible to be treated with abemaciclib after surgery

| Expert 1<br>Recommendation         | Expert 2<br>Recommendation         | Expert 3<br>Recommendation         | Expert 4<br>Recommendation         | Expert 5<br>Recommendation         |
|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| Endocrine therapy +<br>abemaciclib | Endocrine therapy +<br>abemaciclib | Endocrine therapy +<br>abemaciclib | Endocrine therapy +<br>abemaciclib | Endocrine therapy +<br>abemaciclib |

**Case Scenario 5: The experts recommend the following adjuvant therapy for a patient who:**

- Has HR-positive early-stage breast cancer
- Has completed adjuvant chemotherapy
- Will receive adjuvant endocrine therapy with an aromatase inhibitor, along with an ovarian function suppressor for those who were assigned female at birth and have not been through menopause
- Is considered to have a high or very high risk of recurrence
- Tested positive for a *BRCA1* or *BRCA2* mutation, or both
- Is eligible to be treated with either adjuvant abemaciclib or olaparib

| Expert 1<br>Recommendation      | Expert 2<br>Recommendation      | Expert 3<br>Recommendation      | Expert 4<br>Recommendation      | Expert 5<br>Recommendation      |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Endocrine therapy +<br>olaparib | Endocrine therapy +<br>olaparib | Endocrine therapy +<br>olaparib | Endocrine therapy +<br>olaparib | Endocrine therapy +<br>olaparib |

**Additional Expert Comments:** If the patient has disease at a very high risk of recurring, experts recommend giving them abemaciclib after olaparib.



If you are a healthcare professional, you can find our healthcare professional–focused interactive treatment decision support tool here:

[clinicaloptions.com/HR\\_TNBC\\_EBC\\_Tool](https://clinicaloptions.com/HR_TNBC_EBC_Tool)

Patients may also find this tool a useful educational resource.



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