

Breast Cancer Index Is Changing The Game

If you've been diagnosed with early-stage, hormone receptor—positive (HR+) breast cancer, Breast Cancer Index will provide you and your doctor with critical information to aid in the decision on whether you can stop your anti-estrogen therapy at five years, or whether an additional five years of treatment is likely to benefit you.

What is anti-estrogen therapy?

HR+ breast cancer grows in response to estrogen and progesterone. Anti-estrogen therapy is used to prevent these hormones from fueling cancer growth in the body.

There are two main types of anti-estrogen therapy:

- Those that block the action of estrogen on cancer cells in the breast. Tamoxifen is a commonly-used anti-estrogen therapy, and is an example of this type of treatment.
- Those that focus on stopping the body from producing estrogen altogether. Examples of this type of treatment, also called aromatase inhibitors (Als) include anastrozole (Arimidex), letrozole (Femara) and exemestane (Aromasin).
 Aromatase inhibitors are commonly used in treating post-menopausal women.

The standard course of anti-estrogen medication is five years.⁸ But because more than half of recurrences happen after year five from diagnosis,⁹⁻¹¹ your doctor may also recommend your treatment for an additional five years to try to reduce your risk of the cancer returning. Extending your medication may also help prevent the development of new cancers in the other breast.

The challenge:

Nearly 95% of women do not benefit from anti-estrogen therapy after five years.¹⁻⁷



When I learned about
Breast Cancer Index,
I thought, oh my gosh,
I have got to have this test.
I need this information –
am I going to benefit from
another five years of this
medicine? And if I am,
maybe I'll soldier through.
But if there is some
objective test that will
give me that information,
I want it."

Breast Cancer Index Patient



What are my options if the therapy isn't likely to help when considering tolerating an additional five years of therapy and its potential side effects and health risks?

The side effects of anti-estrogen therapy can have a significant impact on daily life and can range from frustrating and uncomfortable to more serious health risks.¹²⁻¹⁶

Possible side effects of aromatase inhibitors: 13-15

- Hot flashes
- · Joint pain and stiffness
- · Vaginal dryness
- Hair thinning
- High cholesterol
- · High blood pressure
- Osteoporosis
- · Bone fractures

Possible side effects of tamoxifen:16

- Mood swings
- · Hot flashes
- · Vaginal dryness
- Weight gain
- · Early-onset menopause
- · Cataracts
- · Blood clots
- · Endometrial cancer
- Stroke

If you are experiencing side effects like these, talk to your doctor about Breast Cancer Index.

Breast Cancer Index is the only test that answers both of the critical questions below to help you and your doctor decide whether continuing or stopping your anti-estrogen therapy after year five is right for you.

- 1. Am I likely to benefit from extended anti-estrogen therapy?
- 2. What is my risk of late distant recurrence?

I thought, I can't do this anymore. I'm miserable. The thought starts to go through your head, is breast cancer worse than having the side effects that I'm having from this drug? When I got my results, I could have danced on the ceiling. I was so happy to know that I wasn't going to have to take this medicine that had really changed my life in ways that I didn't like."

Breast Cancer Index Patient



Starting the Conversation

Regardless of where you are within the first five years of your anti-estrogen treatment, the following questions and information will help you have a more informed conversation with your physician and others caring for you.

Is Breast Cancer Index right for me?

Breast Cancer Index may be right for you if you are looking for more information to help you and your doctor determine your treatment plan beyond year five, and if you:

- Were diagnosed with early-stage, HR+ breast cancer.
- Are pre- or post-menopausal and are lymph node-negative (LN-) or lymph node-positive (LN+) with one to three positive nodes.

•	Want to know whether an additional five years of anti-estrogen treatment will help you reduce your risk of your cancer returning and you are currently disease-free.

When should I ask for the test?

The decision to request Breast Cancer Index may be made at different time points, depending on when you were diagnosed.

- Year five: You're approaching the five-year mark and deciding with your doctor if you should continue or end anti-estrogen therapy.
- Beyond year five: You're wondering if continuing or re-starting anti-estrogen therapy is likely to benefit you.

•	Recently diagnosed: Talk to your doctor about when Breast Cancer Index might be right for you.



Questions to ask yoursel

- Do I want to know if longer anti-estrogen treatment is likely to help keep my cancer from returning?
- Am I taking my anti-estrogen medication as it has been prescribed?
- Do the side effects I am experiencing affect my life?
- · Should I discuss tolerating an additional five years with my physician if it isn't likely to benefit me?
- · Do I have risk factors for any other conditions or complications to consider before making this decision?

•	How do I weigh the side effects of treatment with the potential benefit of another five years?

Questions to ask your oncologist:

- What is my individual risk of breast cancer coming back after five years?
- · Can I lower my risk of the cancer coming back? How?
- Are you recommending I continue or stop my treatment after five years? Why is this your recommendation? Are there other ways to reduce my risk in conjunction with taking anti-estrogen therapy?
- · Will the medication work for me? Which one? How long will I need to take it?
- Is there new data that may affect our decisions about my treatment?
- · What are the potential side effects of my medication?
- · Will my side effects be worse than before?
- · Are there any long-term health concerns related to taking this medication for an extended period of time?
- Which test is best suited to help answer these questions and assist with decision-making?



So, What Happens Next?

Getting the test is a simple, three-step process:

- Ask your oncologist about ordering Breast Cancer Index. Only a licensed physician or an authorized healthcare provider may order the test.
- Your doctor sends your original biopsy tissue to the lab at Biotheranostics, the only lab that offers Breast Cancer Index. You don't need to have another biopsy for this test.
- Once Biotheranostics has received your biopsy tissue and all required information necessary for processing your test, your provider will receive your personalized report in approximately seven days.

We've made the billing process easy.

Once you and your doctor determine Breast Cancer Index is right for you, one of our Patient Service Associates will contact you to walk you through what to expect during the billing process.

Through our Access First program, financial assistance is available for those who qualify. Breast Cancer Index is covered by Medicare with no co-pay or deductible for patients who meet the coverage criteria.

As with all health-related visits, tests, or procedures, you should be aware of your deductibles and co-insurance responsibilities.

Our team of dedicated Patient Services Associates is available to assist you with any questions throughout the process.

Learn more about our billing process and Medicare local coverage criteria on our website:

breastcancerindex.com/contact

Contact Our Patient Services Team

Phone: 844.319.8111

Email: patientservices@biotheranostics.com

For full anti-estrogen prescribing information including, side effects, go to: <u>Tamoxifen | Femara® | Arimidex® | Aromasin®</u> References

1. Goss PE et al., N Engl J Med 2003;349. 2. Goss PE et al, J Natl Cancer Inst 2005;97:1262-71. 3. Jakesz et al., J Natl Cancer Inst. 2007 Dec 19;99(24):1845-53. 4. DaviesC et al., Lancet. 2013;381(9869):805-16. 5. Gray et al., J Clin Oncol 31, 2013 (suppl; abstr 5). 6. Goss PE et al., N Engl J Med. 2016 Jun 5 (Online). 7. Mamounas EP et al. NSABP B-42. S1-05. SABCS 2016 Dec 7, 2016. 8. NCCN Guidelines for Patients®: Invasive Breast Cancer, 2018:50-51. 9. EBCTCG Lancet 2011;378:771-84. 10. Saphner T et al. J Clin Oncol 1996; 14: 2738-46. 11. Cuzick J et al. LancetOncol 2010; 11: 1135-41. 12. Adapted from https://www.breastcancer.org/treatment/hormonal/comp_chart. 13. Femara Full Prescribing Information And Side Effects: https://www.breastcancer.org/treatment/hormonal/aromatase_inhibitors/femara. 14. Armimidex Full Prescribing Information And Side Effects: https://dailymed.nlm.nih.gov/dailymed/druglnfo.cfm?setid=acbfaaa9-503c-4691-9828-76a7146ed6de. 15. Aromasin Full Prescribing Information And Side Effects: http://labeling.pfizer.com/ShowLabeling.aspx?id=523. 16. Tamoxifen Full Prescribing Information And Side Effects: http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682414.html.

Breast Cancer Index Intended Uses and Limitations

The Breast Cancer Index (BCI) Risk of Recurrence & Extended Endocrine Benefit Test is indicated for use in women diagnosed with hormone receptor-positive (HR+), lymph node-negative (LN-) or lymph node-positive (LN+; with 1-3 positive nodes) early-stage, invasive breast cancer who are distant recurrence-free. The BCI test provides: 1) a quantitative estimate of the risk for both late (post-5 years from diagnosis) distant recurrence and of the cumulative distant recurrence risk over 10 years (0-10y) in patients treated with adjuvant endocrine therapy (LN- patients) or adjuvant chemoendocrine therapy (LN+ patients), and 2) prediction of the likelihood of benefit from extended (>5 year) endocrine therapy. BCI results are adjunctive to the ordering physician's workup; treatment decisions require correlation with all other clinical findings. This test was developed and its performance characteristics determined by Biotheranostics, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. Biotheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 to perform high-complexity clinical laboratory testing.



©2019 Biotheranostics, Inc.

