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GENOMICS & YOU GUIDEBOOK

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DEFINITION OF GENOMICS:

Genomics is the study of all of your genes, including how the genes interact with each other and with your environment. With breast cancer, genomics can be used to increase our understanding of this complex disease. For example, the behavior of the breast tumor is affected by activity and interaction of genes in the tumor. Thus, how likely it is that the tumor grows and spreads, how aggressive the tumor is, or how likely it is that the tumor will respond to particular treatment are all dependent on genomics of the tumor.





GENOMICS VERSUS GENETICS:

Genomics and genetics both play a role in health and disease, and both deal with the approximately 20,000 genes in the human body. Genomics is the study of the genome, which is all of your genes. Genetics is the study of specific and limited number of genes or parts of genes that have a known function. Changes in a specific gene may increase your risk for breast cancer, such as BRCA1 gene mutations.

Therefore, while genomics and genetics are both focused on your genes, genomics is a study of all of

the genes and genetics is the study of single genes. Another difference is that genetics looks at how characteristics such as eye color are passed on through DNA from one generation to another generation, while genomics is focused on identifying variations on the DNA that affect health, disease or drug response. The genetics field has been around since the 1860s whereas the genomics field is much newer, with the Human Genome Project being launched in 1990.

GENOMICS IS A STUDY OF ALL OF THE GENES AND GENETICS IS THE STUDY OF SINGLE GENES.

DEFINITION OF PERSONALIZED MEDICINE

Personalized medicine or precision medicine is treatment that is tailored to an individual patient, so that the patient is treated in the most effective manner. In other words, the treatment plan will target your specific breast cancer or the pathways that your tumor cells use to grow and survive. To accomplish this, the medical team considers the genes or other markers on the cancer cells, your genes, your lifestyle factors, and the molecular characteristics of your disease. Testing for personalized medicine may focus on:

- **Drug-Gene Interactions:** Since your genes may influence the way your body processes medications used to treat breast cancer, your doctor may use your genetic information to determine which medications and dosages are most appropriate for you. The field of drug-gene interactions is called pharmacogenomics.
- **Tumor Sequencing:** If your cancer continues to progress despite treatment, your doctor may recommend testing the genetic makeup of your cancer cells. This test, called tumor sequencing, is used to identify changes or alterations in the cancer so that your doctor can choose the best treatment for your specific type of tumor.
- **Genetic Testing:** Mutations in some genes are associated with an increased risk of developing breast cancer compared with the

general population. One example is the BRCA genes. Since BRCA gene mutations are inherited, genetic testing for these types of inherited gene mutations is offered to people with a strong family history of the disease.

HOW IS TREATMENT PERSONALIZED?

To personalize your treatment for breast cancer, several factors are taken into consideration:

- **Size of the tumor** – T0 means that no tumor can be found, Tis means carcinoma in situ, T1 means that the tumor is 2 cm or smaller, T2 means that the tumor is larger than 2cm but smaller than 5 cm, T3 means that the tumor is larger than 5cm, and T4 means that the tumor can be any size but has spread beyond the breast tissue.
- **Type of tumor** – the two breast cancer types are non-invasive and invasive. Ductal carcinoma in situ (DCIS) is a non-invasive type of breast cancer, which means that the tumor cells are contained within the milk ducts of the breast. Invasive breast cancer has spread beyond the breast, possibly to the lymph nodes and/or other parts of the body.
- **Grade of the tumor** – there are 3 grades. Grade 1 refers to well-differentiated cancer cells, which look slightly different from normal cells and grow in slow, well-organized patterns. Grade 2 refers to moderately differentiated





cancer cells that do not look like normal cells and grow and divide faster than normal. Grade 3 refers to poorly differentiated cancer cells that look very different from normal cells and grow quickly in disorganized, irregular patterns.

- **Hormone receptor status of the tumor** – if the tumor is positive for hormone receptors such as estrogen receptor and progesterone receptor (ie., the tumor is estrogen receptor-positive and/or progesterone receptor-positive), hormone therapy might be suitable. On the other hand, if the tumor is negative for estrogen receptor and/or progesterone receptor, hormone therapy might not be suitable.
- **HER2 receptor status of the tumor** – if the tumor is positive for HER2 receptor, anti-HER2 drugs may be suitable. On the other hand, if the tumor is HER2-neg-

ative, anti-HER2 drugs might not be suitable.

- **Menopausal status** – if you have not entered into menopause, you may be eligible to take tamoxifen, however if you are post-menopausal, you can take either tamoxifen or an aromatase inhibitor.
- **Lifestyle factors** – we are increasing our knowledge about this.
- **Genes** – we are also increasing our understanding on how your genes affect breast cancer, and to identify genes that might predict your response to a specific therapy. For example, PARP inhibitors can be more effective for treating metastatic breast cancer if the woman has a *BRCA1* or *BRCA2* gene mutation compared to women without these mutations.

IMPORTANCE OF PERSONALIZED MEDICINE FOR TREATING BREAST CANCER

Breast cancer is a complex disease. It can develop, progress and respond to treatment very differently among patients. Personalized medicine for treating breast cancer provides the most effective treatment as it is tailored to an individual, based on their specific tumor characteristics. This way, the best results are achieved while avoiding unnecessary treatment, risks and side effects.

GENETIC RISK FACTORS ASSOCIATED WITH BREAST CANCER

About 5% -10% of breast cancer cases are associated with abnormalities in genes, which can be passed on from parent to child. Some examples of

genes that may become abnormal and lead to breast cancer are:

- ***BRCA1* and *BRCA2* genes:** *BRCA* gene means **B**reast **C**ancer gene. The normal *BRCA1* and *BRCA2* genes help to repair damaged DNA so that cells can continue to grow and function normally. Mutations in *BRCA1* and *BRCA2* account for about 10% of all breast cancers, and this is considered to be rare. If you have a *BRCA1* mutation or *BRCA2* mutation or both, you may have approximately 40%-70% chance of being diagnosed with breast cancer. Compared to breast cancers without a *BRCA1* mutation or *BRCA2* mutation, breast cancers that are associated with a *BRCA1* mutation or *BRCA2* mutation tend



to be more common in younger women and tend to occur in both breasts.

- **ATM gene:** The *ATM* gene normally helps cells repair damaged DNA. Though rare, mutations in the *ATM* gene have been linked to breast cancer.
- **TP53 gene:** The *TP53* gene normally instructs cells how to make a protein called p53 that helps stop the growth of abnormal cells. Though rare, mutations of the *TP53* gene lead to an increased risk of breast cancer.
- **CHEK2 gene:** The *CHEK2* gene normally helps cells with DNA repair. A *CHEK2* mutation can increase your breast cancer risk.
- **PTEN gene:** The *PTEN* gene normally helps cells grow properly. Though rare, mutations in the *PTEN* gene can increase your risk of developing breast cancer.
- **CDH1 gene:** The *CDH1* gene makes a protein that helps cells bind together. Though rare, a woman with a mutated *CDH1* gene has a 39% to 52% lifetime risk of developing breast cancer.

- **STK11 gene:** The *SK11* gene normally helps cells grow properly. Though rare, mutations in the *SK11* gene may lead to increased risk of developing breast cancer.
- **PALB2 gene:** The *PALB2* gene normally makes a protein that interacts with the protein made by the *BRCA2* gene to ensure that damaged DNA is repaired. Women with a *PALB2* mutation may have a 33% to 53% lifetime risk of developing breast cancer.

PERSONAL RISK FACTORS ASSOCIATED WITH BREAST CANCER

- **Gender:** Women are at higher risk of being diagnosed with breast cancer than men. Approximately 12% of women get breast cancer and 0.1% of men get breast cancer.
- **Aging:** Your risk of developing breast cancer increases as you become older. For women who are diagnosed with breast cancer, 77% are over age 50 and 1% are in their 20s.

WOMEN ARE AT HIGHER RISK OF BEING DIAGNOSED WITH BREAST CANCER THAN MEN. APPROXIMATELY 12% OF WOMEN GET BREAST CANCER AND 0.1% OF MEN GET BREAST CANCER.



- **Family history of breast cancer:** Breast cancer risk is higher among women who have relatives with this disease. This includes your mother, sister, aunt and others.
- **Menstruation before age 12:** If you start your period before age 12, your risk of breast cancer may be higher. This may be because you have been exposed to hormones for longer.
- **Personal history of breast cancer:** If you have had cancer before, you have an increased risk of developing a new cancer in another part of the same breast or in the other breast.
- **Late or no pregnancy:** If you have your first pregnancy after age 30 or if you have never had a full-term pregnancy, you may be at increased risk of developing breast cancer.
- **Race and Ethnicity:** Breast cancer is more common in African-American women under 45 years of age. However, above 45 years old, white women are slightly more likely to develop breast cancer than African-American women.
- **Oral Contraceptives:** Some forms of oral contraceptives (birth control pills) raise breast cancer risk.
- **Dense Breast:** With dense breasts, it is difficult to see abnormalities in the breast tissues. Thus, if you have dense breast and develop breast cancer, it may take longer to detect the breast cancer.
- **Combination Hormone Therapy:** When estrogen and progesterin are taken together for more than five years to replace missing estrogen and progesterone in menopause, your risk of breast cancer increases.





- **Radiation Therapy:** If you have had radiation therapy to the chest or breasts before age 30, you have a higher risk of developing breast cancer.
- **Diethylstilbestrol (DES):** Women who took DES while pregnant to prevent miscarriage have an increased risk for developing cancer.
- **Lifestyle-related factors:** Breast cancer risk can be higher if you are overweight or obese, if you are physically inactive, if you drink alcohol, and/or if you smoke.

HIGH-RISK INDIVIDUALS FOR BREAST CANCER

Some women have a higher chance of being diagnosed with breast cancer. The factors that increase your chances of having breast cancer include having a personal history of breast cancer. If you have had cancer before, you have an increased risk of developing a new cancer in another part of the same breast or in the other breast. In addition, if you have relatives (e, g., your mother, sister, daughter) who have been diagnosed with breast cancer, you have an increased risk of developing breast cancer. A history of breast cancer in your family may be linked

THE FACTORS THAT INCREASE YOUR CHANCES OF HAVING BREAST CANCER INCLUDE HAVING A PERSONAL HISTORY OF BREAST CANCER.

to having an abnormal gene that is passed on over time. For example, mutations in genes such as *BRAC1*, *BRAC2* and *PTEN* are linked to breast cancer, and these mutations can be passed on from parent to child.

BREAST CANCER SCREENING

For women with a personal history of breast cancer, or a family history of breast cancer and/or a family history of abnormal breast-cancer related genes, you should speak with your health care provider to discuss breast cancer

a sample of your blood or saliva is sent to a testing facility. The results are generally ready within two to four weeks. After you receive your results, it is important that speak with the your genetic counselor or healthcare professional to interpret the results and discuss health management options. The cost of testing ranges from \$300 to \$5000 depending on the complexity of the test. Some insurance covers the cost of genetic testing.

THERE ARE GENETIC TESTS AVAILABLE TO DETERMINE IF YOU HAVE MUTATIONS IN GENES THAT ARE ASSOCIATED WITH INCREASED RISK OF DEVELOPING BREAST CANCER.

screening guidelines. The doctor will discuss which screening option may be right for you, whether you need to be screened earlier or more frequently than other women. Some screening options include:

1. Genetic Testing: There are genetic tests available to determine if you have mutations in genes that are associated with increased risk of developing breast cancer. Your doctor or a genetic counselor may order testing for mutations in the following genes individually or as part of a larger panel such as *BRCA1*, *BRCA2*, *ATM*, *CDH1*, *CHEK2*, *PALB2*, *PTEN*, *TP53*. Typically, to perform the genetic test,

2. Screening Frequency: A screening plan for a woman at high risk of developing breast cancer may include:

- breast ultrasound
- monthly breast self-exam
- yearly breast exam by your doctor
- yearly mammogram starting at age 30 or younger
- yearly MRI scan every year starting at age 30 or younger

Women with an abnormal breast cancer gene have a much higher risk of developing breast cancer in between yearly screenings. For example, women with an abnormal *BRCA1* or *BRCA2* gene are





recommended to have a mammogram and an MRI scan each year, about 6 months apart (for example, a mammogram in January and an MRI in July).

PROFILING OF BREAST TUMOR

Like every cell in your body, the cells in a breast tumor have genes that reveal the molecular characteristics of the tumor. This information helps to determine your prognosis and guides treatment decisions. A complete profiling of your breast cancer may include tumor size tumor type, tumor grade, the hormone status of your tumor, the HER2 receptor status of the tumor, and gene mutations.

Determining Hormone Status:

Estrogen and progesterone are a type of protein called hormones that give “fuel” to breast tumor growth. Breast cancers that have high levels of estrogen are called estrogen receptor-positive (ER-positive or ER+). Similarly, breast cancers that have high levels of progesterone are called progesterone receptor-positive (PR-positive or PR+). If the breast cancer has both hormone receptors, it is called ER/PR-positive or ER+/PR+). Your medical team can determine your hormone status as follows:

- **Immunohistochemistry (IHC)** test detects the presence of estrogen and progesterone receptors in the cancer cells. This test is done on a biopsy of your tumor.

Determining HER2 Status:

Human epidermal growth factor receptor 2 (HER2) is a type of protein that is on breast cells. Normally, HER2

receptors help control how breast cell grows, divides, and repairs itself. But in about 25% of breast cancers, the *HER2* gene doesn't work correctly and makes too many copies of itself (known as *HER2* gene amplification). This in turn leads to overproduction of the HER2 receptors, which makes



breast cells grow and divide in an uncontrolled way. Breast cancers that have high levels of HER2 receptors are HER2-positive. Your medical team can determine your hormone status as follows:

- **Immunohistochemistry (IHC)** test detects the number of HER2 protein receptors in the cancer cells. The results of the IHC test can be: 0 (negative), 1+ (also negative), 2+ (borderline), or 3+ (positive),

HER2 protein overexpression).

- **Fluorescence in situ hybridization (FISH)** test detects the number of HER2 genes in the cancer cells. The results of the FISH test can be positive (*HER2* gene amplification) or negative (no *HER2* gene amplification).
- **SPoT-Light HER2 CISH test (Subtraction Probe Technology Chromogenic In Situ Hybridization)** finds out if there are too many copies of the *HER2* gene in the cancer cells. The results of the SPoT-Light test can be positive (*HER2* gene amplification) or negative (no *HER2* gene amplification).
- **Inform HER2 Dual ISH (Inform Dual In Situ Hybridization)** test finds out if there are too many copies of the *HER2* gene in the cancer cells. The results of the Inform HER2 Dual ISH test can be positive (*HER2* gene amplification) or negative (no *HER2* gene amplification).

Determining Genetic Makeup: The genes in breast tumor cells reveal the molecular characteristics of the tumor. This information helps to determine your prognosis and guides treatment decisions. Your medical team can determine the genetic makeup of your tumor using these four tests as follows:

- **BRCAAnalysis CDx** test identifies mutations in the *BRCA1* gene or *BRCA2* gene.
- **Breast Cancer Index** test

examines a group of 11 genes in the tumor cells. It is used to determine treatment decisions for breast cancers that are ER-positive, HER2-negative, and lymph node-negative.

- **Oncotype DX®** test is used to determine the benefit of using chemotherapy in addition to hormone therapy to treat estrogen receptor positive (ER-positive) breast cancers. Oncotype DX is the most commonly used tumor profiling test in the U.S. and it is the only tests that is used in breast cancer staging. Along with other factors, the results of the Oncotype DX test help predict the chance of metastasis for early breast cancers that are ER-positive, HER2 negative, and lymph node negative. Oncotype DX may also be used for some postmenopausal women with invasive breast cancers that are ER-positive, HER2-negative and lymph node-negative when chemotherapy is being considered. If Oncotype DX testing is right for you, your oncologist will review your test results with you and discuss how the Oncotype DX score may guide your treatment plan. Additional details about Oncotype DX are below:

- Tumor testing: Oncotype DX tests a sample of the tumor (removed during a biopsy or surgery) for the activity of a group of 21 genes.
- Tumor staging: Oncotype DX is part of breast cancer



staging for some estrogen receptor-positive, lymph node-negative tumors.

- **Oncotype DX scores:** If your Oncotype DX score is high, this means that you have a fairly high risk of metastasis. Your doctor may recommend a more aggressive treatment plan that includes both hormone therapy and chemotherapy. If your Oncotype DX score is low, this means that you have a low risk of metastasis. Your doctor may recommend the use of hormone therapy alone.

er with an Oncotype DX score showing an intermediate risk of metastasis, TAILORx showed there may be a benefit of including both hormone therapy and chemotherapy in the treatment plan. The Oncotype DX test can also be used for invasive breast cancer has been modified to help predict the chance that ductal carcinoma in situ (DCIS) will return as DCIS or invasive breast cancer by testing a sample of the DCIS tumor for the activity of the group of genes in the test. This test may help identify which cases of DCIS would benefit most from radiation therapy after lumpectomy (and

IF YOUR ONCOTYPE DX SCORE IS HIGH, THIS MEANS THAT YOU HAVE A FAIRLY HIGH RISK OF METASTASIS.

- **Study results:** The National Cancer Institute is using Oncotype DX in a clinical trial called TAILORx to study recently diagnosed patients with hormone receptor-positive, HER2-negative breast cancer that has not spread to the lymph nodes. Recent findings from the TAILORx study show, for some women over 50 with an Oncotype DX score showing an intermediate risk of metastasis, treatment with hormone therapy alone may be as effective as treatment with hormone therapy and chemotherapy. For some women 50 and young-

which women might be treated with lumpectomy alone). This test needs further study and is not yet part of standard practice.

- **MammaPrint test** is used to determine the benefit of using chemotherapy in addition to hormone therapy to treat estrogen receptor positive (ER-positive) breast cancers. It is typically used in breast cancers that have all four of these characteristics: stage I or II, ER-positive, HER2-negative and lymph

IF THE PAM50 TEST SHOWS THE BREAST CANCER HAS A FAIRLY HIGH RISK OF METASTASIS (THE PAM50 SCORE IS HIGH), YOUR DOCTOR MAY RECOMMEND BOTH HORMONE THERAPY AND CHEMOTHERAPY.

node-negative or lymph node-positive with 1-3 positive nodes.

- **Tumor testing:** MammaPrint tests a sample of the tumor (removed during a biopsy or surgery) for the activity of a group of 70 genes.
- **MammaPrint scores:** If the score indicates a fairly high risk of metastasis, your doctor will likely recommend a more aggressive treatment plan that includes both hormone therapy and chemotherapy. If the score indicates a low risk of metastasis, your doctor may recommend treatment with only hormone treatment.
- **PAM50 (Prosigna®) test,** Prediction Analysis of Microarray 50, is used to determine the benefit of using chemotherapy in addition to hormone therapy for some estrogen receptor-positive and HER2-negative breast cancers. Along with other factors, the results of the PAM50 (Prosigna) test help predict the chance of metastasis (when cancer spreads to other organs) and determine the molecular subtype of breast cancer. PAM50 helps predict the chance of metastasis for postmenopausal women with breast cancers that are all of the following: Stage I or II, ER-positive, HER2-negative and lymph node-negative.
- **Tumor profiling:** PAM50 tests a sample of the tumor (removed during a biopsy or surgery) for activity of a group of 50 genes.
- **PAM50 scores:** If the PAM50 test shows the breast cancer has a fairly high risk of metastasis (the PAM50 score is high), a more aggressive treatment, your doctor may recommend both hormone therapy and chemotherapy. If the test shows a low risk of metastasis (the PAM50 score is low), the use of hormone therapy alone may be considered. In this way, PAM50 may help some people avoid chemotherapy and its side effects.
- **Recent findings:** Some findings show PAM50 may help identify which ER-positive breast cancers may benefit from hormone therapy beyond 5 years. However, PAM50 is not recommended for



use in guiding extended hormone therapy use at this time.

TARGETED DRUG THERAPIES FOR BREAST CANCER

Targeted therapy drugs for breast cancer are designed to attack certain cancer cells or certain cellular pathways that cancer cells use to grow and survive. There are several targeted therapies for breast cancer, based on whether they are hormone receptor-positive or HER2-positive. Targeted therapies are also developed for treatment of breast cancer at early stage and at metastatic stage.

About HER2-positive breast cancers.

A number of treatments have been developed to target HER2-positive breast cancers. These include:

- **Trastuzumab (Herceptin):** It may be used alone, but it may also be given along with chemo. Trastuzumab can be used to treat both early- and late-stage breast cancer. For early breast cancer, this drug is usually given for a total of 6 months to a year. For advanced breast cancer, treatment is often given for as long as the drug is helpful.
- **Pertuzumab (Perjeta):** This drug can be given with trastuzumab and chemo, either before surgery to treat early-stage breast cancer, or to treat advanced breast cancer.
- **Ado-trastuzumab emtansine (Kadcyla, also known as TDM-1):** This drug is used by itself to treat advanced breast cancer in women who have already been treated with trastuzumab and chemo.
- **Lapatinib (Tykerb):** Lapatinib is used to treat advanced breast cancer, and might be used along

with certain chemotherapy drugs, trastuzumab, or hormone therapy drugs.

- **Neratinib (Nerlynx):** Neratinib is used to treat early-stage breast cancer after a woman has completed one year of trastuzumab and is usually given for one year. Some clinical trials show that it may also be effective in advanced breast cancer, as well.

that block proteins in the cell called cyclin-dependent kinases (CDKs), particularly CDK4 and CDK6. Blocking these proteins in hormone receptor-positive breast cancer cells helps stop the cells from dividing. This can slow cancer growth. These drugs are approved for women with advanced hormone receptor-positive, HER2-negative breast cancer. Some examples include:

NERATINIB IS USED TO TREAT EARLY-STAGE BREAST CANCER AFTER A WOMAN HAS COMPLETED ONE YEAR OF TRASTUZUMAB AND IS USUALLY GIVEN FOR ONE YEAR.

About Hormone receptor-positive breast cancers. Treatments that target hormone receptor-positive breast cancers include Everolimus (Afinitor) and CDK4/6 inhibitors.

- **Everolimus (Afinitor)** has been approved for women who have advanced hormone receptor-positive, HER2-negative breast cancer and have gone through menopause. Everolimus is used along with the aromatase inhibitor exemestane (Aromasin) for women whose cancers have grown while being treated with either letrozole or anastrozole (or if the cancer started growing shortly after treatment with these drugs was stopped).
- **CDK4/6 inhibitors** are drugs

that block proteins in the cell called cyclin-dependent kinases (CDKs), particularly CDK4 and CDK6. Blocking these proteins in hormone receptor-positive breast cancer cells helps stop the cells from dividing. This can slow cancer growth. These drugs are approved for women with advanced hormone receptor-positive, HER2-negative breast cancer. Some examples include:

- **Palbociclib or abemaciclib** can be given with fulvestrant to women who are premenopausal (still having regular periods) or are almost in menopause (perimenopausal). These women, however, must also be on medications, such as luteinizing hormone-releasing (LHRH) analogs that stop the ovaries from making estrogen.
- **Ribociclib** can be given with an aromatase inhibitor (such as letrozole) to women who



have not gone through menopause. As with palbociclib or abemaciclib, these women must also be using medicines that suppress the ovaries.

- **Abemaciclib** can be used by itself in women who have previously been treated with hormone therapy and chemotherapy.

About Breast cancers with *BRCA* gene mutations. Treatments that target breast cancers with *BRCA* gene mutations are PARP inhibitors. PARP proteins normally help repair damaged DNA inside cells. The *BRCA* genes (*BRCA1* and *BRCA2*) also help repair DNA (in a slightly different way), but mu-

tations in one of those genes can stop this from happening. PARP inhibitors work by blocking the PARP proteins. Because tumor cells with a mutated *BRCA* gene already have trouble repairing damaged DNA, blocking the PARP proteins often leads to the death of these cells.

- **Olaparib (Lynparza) and talazoparib (Talzenna)** can be used to treat metastatic, HER2-negative breast cancer in women with a *BRCA* mutation who have already gotten chemotherapy. Olaparib can also be used in women who have already received hormone therapy if the cancer is hormone receptor-positive.



THE ONCOTYPE DX TEST

The Oncotype DX Test is a genomic test that evaluates specific genes in your breast tumor to provide information that your doctor can use to develop a personalized treatment plan for you. If you have early-stage invasive breast cancer, Oncotype DX test predicts the likelihood that you may benefit from chemotherapy, and the likelihood of your cancer returning. If you have ductal carcinoma in situ (DCIS), the Oncotype DX test predicts the likelihood of your cancer returning in the same breast. The Oncotype DX test is a product of Genomic Health.

IS ONCOTYPE DX FOR YOU?

You may be a candidate for the Oncotype DX test if:

- you have recently been diagnosed with stage I breast cancer or stage II invasive breast cancer
- the cancer is estrogen-receptor-positive
- there is no cancer in your lymph nodes (lymph-node-negative breast cancer)
- you and your doctor are making decisions about chemotherapy

QUESTIONS TO ASK YOUR DOCTOR ABOUT ONCOTYPE DX

The Oncotype DX test must be ordered by your doctor or a licensed healthcare provider. You and your doctor will decide if the Oncotype DX test is right for you. Some questions that you may want to ask your doctor include:

- What stage is my breast cancer?
- What are the chances of my cancer coming back after surgery?
- Is my breast cancer hormone receptor-positive (ER+ or PR+)?
- What are my treatment options? What do you suggest for me and why?
- What are the benefits of each treatment option? What are the drawbacks/side effects of each one?
- How long do side effects of each treatment option last? Do side effects go away once treatment is complete?
- Is it OK to wait a few weeks to consider my treatment plan options before I have to make a decision about treatment?
- Am I a candidate for the Oncotype DX test?
- If I am a candidate for the Oncotype DX test, how could we use the test results to develop my treatment plan?
- How can I get a copy of my pathology report and my Oncotype DX test results (if I'm eligible for the test)?

TAKE THE ONCOTYPE DX ELIGIBILITY QUIZ

1. Are you a newly diagnosed breast cancer patient or caregiver trying to determine what treatment plan is right for you or a loved one?
 - Yes.
 - No.

2. What stage is your breast cancer?
 - Stage 0 DCIS (non-invasive breast cancer).
 - Stage I.
 - Stage II.
 - Stage IIIa.
 - Stage IIIb or above.
 - I am not sure.

3. Has your breast cancer been diagnosed as estrogen receptor positive (ER+)?
 - Yes.
 - No.
 - I am not sure.

4. Does your breast cancer have lymph node involvement?
 - No.
 - Yes. One to three lymph nodes are positive.
 - Yes. More than 3 lymph nodes are positive.
 - I am not sure.

ADDITIONAL RESOURCES:

ONCOTYPEDX GUIDES

Genomic Health has several free guides for Oncotype DX. For DCIS Breast Cancer, see Doctor Discussion Guide for DCIS Breast Cancer, DCIS Breast Cancer Patient Guide, and Patient Guide to DCIS Surgery. For Invasive Breast Cancer, see Doctor Discussion Guide for Invasive Breast Cancer, Invasive Breast Cancer Patient Guide, Patient Guide to Early-Stage Invasive Breast Cancer Surgery and Treatment and Invasive Breast Cancer Patient Guide (Spanish). For general knowledge, see Recently Diagnosed – Inform Yourself.

MOBILE BREAST CANCER APPS

Mobile Breast Cancer Apps are convenient tools for guiding breast cancer patients, survivors and caregivers. Some examples are:

1. **My Cancer Coach:** Includes calendar, note-taking, audio-recording. It has a list of questions to ask your doctor. My Cancer Coach is available for iPhone and Android.
2. **NCCN Reimbursement Resource:** Provides access to payment assistance and reimbursement programs for covering cancer-related charges. NCCN Reimbursement is available for iPhone and Android.
3. **Caring Bridge:** Connects you with the support of family and friends. Caring Coach is available for iPhone and Android.
4. **Pills on the Go:** Provides reminder to take your medications. Pills on the Go is available for Android.
5. **CareZone:** Helps to manage daily appointments, medications, school practices and contacts. CareZone is available for iPhone and Android.
6. **Breast Check Reminder:** Provides reminder to perform monthly breast self-exam. Breast Check is available for iPhone and Android.
7. **Breast Self-Exam:** Helps you track changes that you detect when you are conducting your monthly breast self-exam. Breast Check is available for Android.
8. **Breast Cancer Ribbons:** Provides a variety of positive wallpapers and messages to help you stay strong and inspired during your breast cancer journey. Breast Cancer Ribbon is available for iPhone.

LINKS AND VIDEO RESOURCES

Genomic Health has a library of videos and websites that provide additional information about breast cancer and treatments. This library also provides guidance for personalizing your breast cancer treatment with Oncotype DX. There are videos about DCIS Breast Cancer, Invasive Breast Cancer and Oncotype DX score, results. There are links to Advocacy, Education and Support, Clinical Trials, Answers from Breast Cancer Experts, Advanced Breast Cancer Information and Breast Cancer Blogs.



GLOSSARY

Biomarker: A biomarker or molecular marker is a biological molecule found in blood, other body fluids or tissues.

Biopsy: Biopsy is the examination of tissue removed from a living body. For example, a biopsy of breast cancer is taken to examine the characteristics of the tumor.

Clinical trial: A clinical trial is a type of medical research study that determines whether an intervention – a new drug, medical device or diagnostic tool – is safe and/or effective.

Companion Diagnostic: A companion diagnostic is a test or measurement that can be used to determine the efficacy and/or safety of a specific drug for a targeted patient group or patient sub-groups.

DNA: Deoxyribonucleic acid or DNA is a cellular component that contains the instructions for most forms of life.

Epigenomics: Epigenomics takes into account how factors, such as the environment, can result in changes in gene expression.

Gene Mutation: This is permanent change in the DNA sequence that makes up a gene. Gene mutations may be inherited from a parent or acquired during a person's lifetime.

Gene testing: Genetic testing is performed with a laboratory test to identify genetic changes associated with a disease.

Genetic Counseling: A healthcare professional with specialized knowledge of genetics meets with an individual or family to determine if a condition in the family is genetic and estimate the chances that another relative may be affected. Genetic counseling may also involve performing and interpreting genetic tests that estimate disease risk, as well as conveying information so as to help address concerns of the individual or family and provide psychological counseling to help them adapt to the condition or risk.

Genetic Marker: A genetic marker is an alternation in DNA that may indicate an increased risk of developing breast cancer.

Genome: The genome is the complete genetic material of an organism.

Genomic Sequencing: Genomic Sequencing is a method to determine the entire genetic makeup of a single cell or of an entire organism. This method can help determine changes in DNA that may lead to the development of breast cancer.

Genomics: Genomics is the study of the genome – structure, function, evolution and mapping.

GINA: The Genetic Information Nondiscrimination Act or GINA is a federal legislation that prohibits discrimination against individuals on the basis of their genetic profiles in regard to health insurance and employment. The law was passed in 2008.

Personalized medicine: This refers to treatment that is tailored to an individual patient, so that the patient is treated in the most effective manner. Diagnostic tools are used to identify specific biological markers to help determine which medical treatments and procedures will be best for the patient.

Pharmacogenomics: Pharmacogenomics is the field that examines how your genes influence the way your body processes medications used to treat breast cancer.

Proteomics: Proteomics is the analysis of protein structure and function.

Risk factors: A risk factor is a characteristic or exposure of an individual that increases their likelihood of developing breast cancer.

Targeted therapy: Targeted therapy is drugs for breast cancer that are designed to attack certain cancer cells or certain cellular pathways that cancer cells use to grow and survive.

Tumor sequencing: Doctors can sequence the DNA from your cancer cells to identify which mutations are responsible for causing breast cancer.



NOTES

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