Metastatic Breast Cancer Guide

Look inside for details on accessing alternative options and Federal workplace protections.

Breast cancer can happen to anyone, regardless of whether they are old or young, male or female, or whether or not they have high or low risk factors. Breast cancer is considered *Metastatic*, or Stage 4, when there is evidence cancer cells have spread to areas outside the breast or nearby lymph nodes. Metastatic breast cancer patients are likely to have symptoms that affect other organs of the body, including the bones, lungs, liver or brain, where the cancer cells grow and multiply.

Metastatic breast cancer patients along with their caregivers face complex medical situations with accompanying financial challenges, intricate treatment decisions, long-term workplace and employment concerns and many other unique issues. While metastatic breast cancer cannot be cured, it *can* be treated and managed allowing the patient many quality years of life ahead. This guide is designed to provide practical advice to patients and their loved ones as they live with a metastatic breast cancer diagnosis.

This guide delivers expert advice specifically for Metastatic Breast Cancer patients to help avoid common insurance and care barriers.

Engaging With Your Medical Team

When faced with a metastatic breast cancer diagnosis or a recurrence of breast cancer, there are many aspects to consider such as available treatment options and utilizing a proactive strategy to reduce insurance barriers.

As a metastatic patient, you will likely start to hear numerous new medical and technical clinical terms. To help make sense of your situation, consider these tips when discussing your treatment:

- Write down your questions before your visit. List the most important ones first to ensure they are answered, and write down the answers in case you forget.
- If you don't understand what the healthcare team is recommending, ask to speak with an oncology nurse to discuss your concerns.
- Consider electronically recording the visit so you or a family member can refer to it later.
- Bring someone with you to your appointment. They can ask questions you may not think of and help you take notes.
- Ask your provider to show you diagrams or drawings that may help increase your understanding.

Learn more about your treatment team by asking the following questions:

- How long have you been treating people with breast cancer?
- How many metastatic breast cancer patients do you treat each year?
- What has been your experience with the results of this treatment?
- How will my treatment affect my daily activities?
- How do you stay up to date on the latest treatment options and medical advances?
- Do you enroll patients into clinical trials should I want to participate in one?
- Who do you recommend I see for a second opinion?
- Would you consider having genomic testing done on my tumor?

Potential Insurance Complications with Chemotherapy

Many new medications are available orally offering the patient the option for home-centered treatment. However, for treatment such as chemotherapy, which is offered both with intravenous infusion and oral pills, each form may be categorized differently by the insurance company. For example, intravenous chemotherapy is normally covered under the medical benefit of your insurance plan, while oral medications are covered through the prescription benefit of your insurance plan. If you are prescribed the oral form, this means you are responsible for your drug pharmacy co-pay before you can pick up your prescription.

If you and your oncologist determine that oral chemotherapy is your best treatment option, you may find it challenging to afford the high out-of-pocket expenses. Explore co-payment assistance programs or other financial assistance options.

Understanding Treatment Options

Most treatment for metastatic breast cancer works to prevent or slow the disease progression while easing symptoms and managing treatment side effects. There are several forms of treatment for metastatic breast cancer patients. Your treatment history and response to therapy will determine the type of treatment your doctor may recommend.

If you have been diagnosed with metastatic breast cancer, call your insurance company and enroll in a case management program. Charged with coordinating your care, case managers bridge the gap between you, your medical providers and the insurance company, tackling any healthcare roadblocks you may encounter.

Hormone Therapy – prevents cancer cells from receiving estrogen, thus halting their growth. This is usually the first treatment option for hormone receptor-positive patients.

Targeted Therapy – designed to attack a certain molecular agent or pathway responsible for cancer development.

Radiation Therapy – targets the tumor to kill the cancer cells and can provide relief from the pain associated with the cancer.

Chemotherapy – treatment that attacks all cells indiscriminately in the hope of reducing the growth of rapidly dividing cancer cells. Available intravenously or via pill form, this treatment can be prescribed alone or in combination with other treatment.

Surgery – a provider manually removes the tumor and its surrounding tissue from your body. Two types of common breast cancer surgery are called "lumpectomy" and "mastectomy." Surgery is frequently no longer a viable treatment option alone during the metastatic stage because the cancer has spread beyond the confines of the breast.

Options to Access Alternative and Emerging Treatment Options

Researchers today are discovering new treatment options that target specific genetic changes in cancer cells. These new protocols can provide you and your physician the ability to customize treatment based on your unique tumor type and genetic mutations. This method has also been found to reduce exposure to ineffective or less effective treatment protocols.

Clinical Trials – Clinical trials offer the ability to access an emerging treatment option otherwise unavailable outside of the trial. Clinical trials are conducted in a series of steps, called phases and many times contain medication that has shown promising results in research.

A clinical trial may require travel so it is important to consider transportation, lodging and food expenses. Some clinical trials will cover those expenses but only if requested by the patient. If you are working while accessing treatment via clinical trials, consider activating any workplace protections you may be eligible for, including protected leave under the Family Medical & Leave Act and applying for short- and long-term Disability benefits to protect your income during extended absences from work.

Accessing Investigational Drugs - If you do not qualify for a clinical trial, you may consider requesting treatment through an "Expanded Access" program (also known as "compassionate use").

This option allows patients access to effective investigational drugs that are in Phase 3 or beyond of the clinical trial stage. Although these treatment options may not yet have been approved by the Food and Drug Administration, to access, there must be reasonable evidence that the risk of the drug is not greater than the risk from the disease and that the drug will prolong survival or improve your quality of life.

In this situation, your insurance may not cover the cost of the treatment or drugs to address any side effects. You may find it helpful to discuss treatment options and financial obligations with your insurance company or case manager if considering an Expanded Access program.

Genetic and Genomic Testing

Incorporating knowledge specific to the individual genetic makeup in your body as well as your exact cancer as part of your treatment plan can be highly beneficial and lend itself to more informed and targeted decisions on care. This concept, called "personalized medicine" is a rapidly developing field of treatment within the cancer community. The "Genetic" and "Genomic" terms are very similar but actually refer to different types of information.

Under provisions of the Affordable Care Act, new health plans are required to pay for genetic counseling and genetic testing for women who have a demonstrated high risk of having the BRCA gene.

Genetic Testing is performed on blood or tissues of an individual to identify abnormalities or alterations in your genes that, if present, can identify your risk for developing a particular disease or type of cancer. This analysis of your individual DNA can detect inheritable genes and chromosomes that have been found to be linked to a higher risk for hereditary disorders. For example, a defective BRCA (breast cancer) gene increases the odds that you will be susceptible to breast or ovarian cancer over the course of your life. Genetic testing can be done on patients of all ages or who do not show any signs of illness. If a gene mutation is positively identified, it does not mean that the patient will definitely be affected by the condition.

Biomarker Testing may be completed with genetic testing. Biomarkers refer to the molecules found in all blood or tissues and that can be measured to indicate an abnormal condition or disease. Depending on the specific biomarker, this genetic testing can be used to identify risk of a disease, early detection through screening or even help diagnosis a specific cancer type.

Genomic Testing is done on a cancer tumor itself and looks for specific mutations that are present within the cancer cells. Results can provide valuable information on how your specific cancer cell is behaving, and this information can be used to match treatment found effective against reducing or killing that cellular behavior. Many times genomic testing also identifies ineffective treatment options that can be avoided by your doctor. Talk to your insurance company for coverage details about whether your plan will cover genomic testing related to your breast cancer. If your insurance company will not cover the testing, reach out to the manufacturer of the test to inquire about the availability of financial assistance to help cover the cost.

Qualifying for Government Benefits

Social Security Disability Insurance (SSDI)

Immediately upon diagnosis of metastatic breast cancer (stage IV), you are eligible to apply for disability benefits under the Compassionate Allowances program. The program is intended to expedite the processing of Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI) claims for applicants whose medical conditions are so severe that their conditions are known to meet the Social Security's definition of disability. Decisions are usually expedited depending on how quickly you submit the requested information and medical documentation arrives from your doctor.

In most cases, after 24 months of receiving SSDI benefits, you are eligible for Medicare insurance benefits regardless of age.

Compassionate Allowance speeds the application and disability designation; however, even when found disabled by SSDI, you will not begin to receive your disability checks until the beginning of the sixth month after your disability date.

Supplemental Security Income (SSI)

SSI is a separate governmental program that provides benefits to people who are disabled and have very little income and assets. SSI provides monthly payments to low-income individuals who do not qualify for SSDI because they have either never worked or who have insufficient credits on their earnings record. If you qualify for SSI benefits in most states, you are also eligible for Medicaid benefits.

Request the PAF guide on **Maintaining Eligibility for Insurance** *for more information on benefits and protections.*

Federal Workplace Protections Critical to Employed Metastatic Breast Cancer Patients

The **Family and Medical Leave Act (FMLA)** exists to help patients maintain employment and employer-based health insurance benefits while being treated for serious illness. This protection allows you to take up to 12 weeks of unpaid leave from work related to your diagnosis and be eligible to return to work. You must provide documentation from a physician that supports the request for leave and provide this to your employer. Once approved, leave can be taken in one large block, or a few hours at a time. FMLA is calculated and recorded annually and can be renewed the following year if a qualifying medical condition continues.

It is important to know that not all employers are required by law to offer FMLA leave. Consult with your human resources department about your company policy.

Employers have the right to require that you use any available paid vacation and sick time before you are allowed to take unpaid FMLA leave. When you return to work, your employer must return you to your original position or an equivalent job with the same pay, benefits and other employment terms.

FMLA also protects caregivers and family members who assist you during your journey, and provides them the option for protected leave to support you during your medical journey.

The **Americans with Disabilities Act (ADA)** protects the privacy of metastatic breast cancer patients and provides an avenue to request accommodations that support your ability to remain in the workforce.

Under the ADA law, employers cannot inquire whether you have cancer or any other medical condition upon interview or during the hiring process. ADA also protects your privacy if you do share your medical information at a later point to your employer, as your employer may not share this information with unauthorized colleagues.

Once employed, the ADA also allows patients the right to request an accommodation related to your treatment. Examples of reasonable accommodations include the ability to take periodic breaks or have access to a private area to take medication, the ability to have a modified work schedule or shift change, the ability to leave for doctors appointments, permission to work from home, modified work environment temperature or permission to use work telephone to call doctors and coordinate care.

If you have exhausted the 12 weeks of leave allowed under FMLA, and you are not yet ready to return to work, ADA provides another avenue to request extended leave as an accommodation.

Additional provisions specific to cancer patients may be found at the Equal Employment Opportunity Commission website: *http://www.eeoc.gov/laws/types/cancer.cfm.*

Addressing Areas of Your Care that May be Hard to Face

Maintaining comfort and trust in your medical team

It is important to be comfortable when speaking with your healthcare team. If you are not getting the information you need, you dislike the doctor, your doctor is in an inconvenient location or you are not satisfied with what you are being told, you may want to consider finding a new physician. The doctor-patient relationship has been shown to be critical to overall patient outcomes, so do not feel awkward or embarrassed if you want to seek another provider.

Discussing costs with your doctor

If you find it challenging to pay for your treatment, discuss financial concerns with your treatment team. Being honest about any anxiety related to cost with your doctor may open up a dialogue that ultimately allows you to connect with additional options.

There are financial assistance programs available to assist with your medication and treatment co-payments through nonprofit organizations or through your medication's manufacturer. If you are employed, you may be able to recover some costs through a flexible savings or health savings account that can accompany your health insurance plan. You may also find a list of grant or financial assistance programs on breast cancer support websites that can help.

Legal paperwork relevant to patients

Advanced Directives, also known as living wills, are a set of written instructions that communicates your treatment preferences to your healthcare team and family members in a situation where you are incapable of making the decision. This assures that your wishes are carried out and relieves some of the decision-making burden from your loved ones. You do not need to have an advanced directive to authorize a "do not resuscitate" (DNR) order in your medical record, but you will need to make this known to your medical providers in order for it to be documented.

Power of Attorney is a document that gives someone the authority to handle all financial, legal and/or health affairs if you are unable to do it for yourself. You need to trust the person you select is both able and willing to perform these duties during these critical and emotional times. Be sure that you discuss your wishes with them in detail and alert them of this documentation so that they are prepared to execute your choices.

You can also designate a **Medical Power of Attorney** to someone to make medical decisions for you without giving them the authority to handle your financial or legal affairs.

These distinctions are relevant during the period you are receiving medical care. Unless otherwise documented, these powers will expire at the time of your death and will not carry over to allow decisions related to your estate and burial.

Beyond active treatment

The goal of **Palliative Care** is to focus on quality of life during long-term medical care. Palliative care can be given alongside any other forms of active treatment you are receiving to treat your cancer, and be relevant at any point in your treatment journey. The palliative care team helps manage symptoms or side effects you may encounter during treatment.

Palliative care may be covered under the hospice benefit, standard medical benefits of your insurance plan, or contained within long-term care insurance plans.

Inquire about out-of-pocket responsibilities before you agree to receive services. Palliative is distinctly different than hospice care, although it is frequently confused with other end-of-life services.

Hospice Care is available to those whose life expectancy is six months or less. Hospice care focuses on maintaining comfort when there are no curative treatments available or when you make the personal choice not to continue treatment. Care is available at home or in a care facility. Hospice staff members are there to support you and your family members with your preferred end-of-life care. Hospice teams provide medical care, emotional support and spiritual resources to people in the last stages of a terminal illness. Hospice benefits are available under most insurance policies. The hospice benefit usually includes all services, medications and equipment necessary to treat the hospice diagnosis.

Breast cancer can happen to anyone, regardless of whether they are old or young, male or female, or have high or low risk factors.

Vocabulary to Know

Adjuvant Therapy:
Treatment given after removing the cancer with surgery.

BRCA:
Breast Cancer susceptibility genes make proteins that help control cell growth. If you have a family history of breast or ovarian cancer genetic testing can identify your chances of developing those cancers.

Estrogen Receptor:
A protein found inside some cancer cells that is stimulated by the hormone estrogen and is dependent upon estrogen to grow. Also called ER.

Expanded Access:
A program started by the FDA that allows certain promising investigational therapies to be made available to people with serious or life-threatening illnesses without other treatment options, before being formally approved for use.

Food and Drug Administration (FDA):
An agency in the federal government responsible for ensuring drugs, medical devices, and equipment are safe for use in the United States.

Gene Therapies:
Therapies that alter the genetic structure of a tumor cell, making them more susceptible to either the immune system or chemotherapy.

Hormonal Therapy:
Treatment that adds, blocks, or removes hormones. To slow or stop the growth of breast cancer, synthetic hormones or other drugs may be given to interfere with the body's ability to stimulate the growth of breast cancer cells.

Human Epidermal Growth Factor Receptor 2 (HER2):
A protein that controls how cancer cells, grow, divide and repair themselves. HER2 positive indicates that your cancer may respond to targeted hormonal therapies.

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Vocabulary to Know

Monoclonal Antibody:
A type of protein made in a laboratory to bind to a particular substance in the body, including cancer cells. They can be used alone or to carry drugs, toxins or radioactive materials directly to cancer cells.

Mutation:
Any change in the DNA sequence of a cell. Mutations can be harmful, beneficial or have no effect. Certain mutations may lead to cancer or other diseases.

Progesterone Receptor:
A protein found inside some cancer cells that are dependent on progesterone to grow. Also called PR.

Relapse or Recurrence:
A return of cancer after treatment or after a period of time during which the cancer cannot be detected.

Targeted Therapy:
A type of treatment that uses drugs and antibodies to attack specific types of cancer cells with less harm to normal cells. Some targeted therapy blocks the action of certain enzymes, proteins or other molecules involved in the growth and spread of cancer cells. These treatments can be given alone or in combination with chemotherapy.

Triple Negative:
This cancer tests negative for estrogen, progesterone and the HER2 protein. These tumors are not responsive to current targeted therapies, although they usually respond well to chemotherapy.

Tumor Response:
The shrinking of a tumor following treatment.

Helpful Resources

Advanced BC.org
www.advancedbc.org

BC Mets.org
www.bcmets.org

Breast Cancer Trials
www.breastcancertrials.org

BreastCancer.org
www.breastcancer.org

Cancer and Careers
www.cancerandcareers.org

Cancer Care
www.cancercare.org

Cancer Connect
www.cancerconnect.org

Cancer Support Community
www.cancersupportcommunity.org

FORCE: Facing Our Risk of Cancer Empowered
www.facingourrisk.org

Know Your Breast Cancer
www.knowyourbreastcancer.com

Lazarex Cancer Foundation
www.lazarex.org

Living Beyond Breast Cancer
www.lbbc.org

Men Against Breast Cancer
www.menagainstbreastcancer.org

Metastatic Breast Cancer Network
www.mbcn.org

METAvivor
www.metavivor.org

My BC Team
www.mbcnetwork.org

National Cancer Institute
www.cancer.gov
www.cancer.gov/clinicaltrails

National Underinsured Resource Directory
www.patientadvocate.org/underinsured

Nueva Vida
www.nueva-vida.org

Patient Resources, Inc.
www.patientresource.com/Metastatic_Breast.aspx

Pink Link Breast Cancer Social Network
www.pink-link.org

SHARE
www.sharecancersupport.org

Sharsheret
www.sharsheret.org

Sisters' Network
www.sistersnetworkinc.org

Susan G. Komen
ww5.komen.org

Triple Negative Breast Cancer Foundation
www.tnbcfoundation.org

Triple Step Toward The Cure
www.triplesteptowardthecure.org

Young Survival Coalition
www.youngsurvival.org

Caring for Your Emotional Side

Learning that you have metastatic breast cancer can be an overwhelming experience – one that leaves you feeling numb, frightened, vulnerable and alone even when you are surrounded by family and friends.

This is a time where you need to put yourself first.
Metastatic breast cancer is treatable even if not curable. Become informed about all of your treatment options, and have a clear head when you are making decisions regarding how you want to proceed.

It's important to know that feeling stressed and anxious is normal. Talking to someone may be the first step in helping you live well with metastatic breast cancer. You may feel like you should stay strong but it is also important for you to find people who have experience in what you are facing, can comfort you and are available to share their story. Trying to carry this burden alone while pretending everything is fine is not a good idea and can impact your overall health.

Be honest with your treatment team about any emotional strains and how you are feeling, as there may be support services directly provided by your cancer treatment center and available to help you and your family members. Another option is to take advantage of counseling benefits available through your insurance plan, as this may be a way to express yourself without feeling a burden of sharing with those affected personally by your diagnosis. And lastly, there are many cancer organizations that offer emotional support, including in-person support groups, one-on-one 24/7 phone support, connection to a mentor or fellow survivor, or online disease-specific forums to guide you through the process.

Advocates Share the Basics to Help You Decide if a Clinical Trial Is Right For You

Clinical Trials:

What Patient Advocates Want You to Know

Clinical Trials Are Definitely Worth a Second Look for Any Patient

Patient advocates help patients avoid and fix roadblocks and work to ensure timely and affordable access to prescribed treatment and medication as part of their healthcare.

When working with patients, no matter what the problem is, experienced advocates know that its not surprising that the option of clinical trials frequently comes up in the conversation as a possible solution. But what is surprising to so many of us who work alongside patients everyday, is the lack of accurate information surrounding this source of advanced treatment. Not only are patients too often unaware of the benefits of clinical trials, but many are also quick to dismiss the suggestion as a feasible avenue relying solely on inaccurate or limited information.

In this guide, advocates from Patient Advocate Foundation bring forward some of the less known and frequently misunderstood benefits of clinical trials and address the most frequently asked questions from patients.

We encourage all patients, and those at high risk of developing disease, to learn more about how they can benefit from trials, and maybe add it to the list of care options to consider in their future.

Its just too important of an option for advanced care that many patients are bypassing without realizing it.

> 100% of current FDA approved treatment went through a clinical trial, giving those first patients exclusive access to the benefits when others couldn't get it.

Trials Are Not Just For Treatment

Some people only think of clinical trials for last resort treatment options, when other treatments have failed. Not only are many treatment trials geared towards those who have just been diagnosed, there are also numerous trials that are improving other aspects of our healthcare. There are six categories of clinical trials each designed with specific goals in mind:

Treatment trials study new drugs, techniques, surgeries or combinations of treatments for those in any stage of disease.

Prevention trials discover ways to keep from getting a specific disease, and look to identify specific genetic or inherited risk factors.

Screening trials explore new ways to detect diseases or conditions.

Diagnostic trials explore better testing procedures for an illness or condition.

Quality-of-Life trials evaluate ways to improve patient comfort, including addressing ways to reduce or eliminate side effects of treatment.

Observational studies determine long term health outcomes by monitoring data over time.

PAF Patient Advocate Foundation

patientadvocate.org
(800) 532-5274

What Is the Purpose of a Clinical Trial?

Clinical trials are carefully designed science-driven studies that test the benefits and risks of specific medical treatments or interventions to prevent, treat or monitor disease, including items such as a new drug or behavior change (e.g. diet).

Clinical trials are at the forefront of medical advancements against all types of disease, including breast and metastatic breast cancer. Every standard treatment and medicine available today was proven to be effective as a result of going through the clinical trial process. The ultimate goal of clinical trials is to determine if the new treatment, drug or process being studied is safe and as effective to replace or add to the current treatment being offered today.

What Does Participation Mean Exactly? Is it Right For You?

You may be curious about learning more about clinical trials to explore whether volunteering to participate makes sense for you. Each trial is designed and monitored to ensure patient safety and is ultimately a step in the path to treat or cure disease, however every aspect of medical care also includes risks and may be different for everyone. While some people may consider a specific aspect a benefit, others consider the same element a concern, so it is important to weigh each as it relates to your situation.

- You get it first -- Trial participants are given the opportunity to be among the first to benefit from a new treatment being studied that is otherwise not available outside of the trial.
- You will be more involved - trial participants tend to be more informed every step of the way, meaning they play an active role and gain a greater understanding of their disease or condition.
- More signatures - You are likely to have more paperwork to review for a trial and more to read. Plus, more medical details (and disclaimers) are shared with you during the process than you might have with the standard treatment.
- Everyone benefits - Participants volunteer and ultimately help advance medical research for other patients, even if they don't directly benefit from the results of the specific clinical trial.
- Possibility of better results - You could have better results, less side effects or both compared to the usual care.
- Experts for your diagnosis - Trials are done by cutting edge research teams of doctors and specialists who understand your disease and work with patients just like you everyday.
- Close monitoring - You may require additional tests, monitoring or doctor visits than if you were not in a trial. Some patients find this reassuring while others find it a burden.
- Shared costs - The costs for any trial specific items are paid by the trial sponsor, and some additional non-medical costs may be eligible for reimbursement as part of the trial.
- Locations vary - Some trial locations are online, nearby or even conducted by your current doctor. But sometimes the trial location may not be available at a location that is convenient to you, meaning you have more travel needs or have to change doctors.
- Not always better - Sometimes the new treatment or new process being investigated will not have any better results than the current standard treatment, or enough better results to be worth expanding to future patients.
- A lot is still unknown - The way you will respond is not as predictable as standard treatments. This means that you may have fewer side effects or you may have unexpected or more side effects. Early phase trials will have less information for the doctor to tell you what to expect than later trials. This is also why there is likely to be a requirement to bring someone with you for every treatment.
- Costs can fall through the cracks - Even when you ask upfront, there may turn out to be expenses that your insurance and the trial sponsor may not pay and you must pay. Laws do require your insurance to cover services associated with routine care including what you would normally have covered outside of a trial for your diagnosis.
- Random means random - Cancer trials rarely involve a placebo, (and you must be notified if your study involves one), however in randomized trials you will not get to choose whether you have the standard treatment or the standard plus the trial-specific care.

The total number of registered studies has grown 4600% since the year 2000. With over 260,000 medical studies active in 2017, millions of patients are enrolled with access to cutting edge medicine.

Understanding the Differences in Study Phases

There are 3 ways that clinical trial research is structured known as phases, that must take place before a medical care option can be sold and marketed to patients. Each phase is designed to fine tune the answers to separate research questions. The knowledge gained by each stage together helps ensure that the product or procedure will benefit large populations after approval.

Phase 1 involve a small group of people and are the first studies done to test if a new option is safe, identify possible side effects and to look for the best way to give the treatment (by mouth, injected into a vein, or injected into the muscle). Researchers also look for signs that diseased cells respond to the new treatment.

Phase 2 enrolls a larger group of people to see if the diseased cells respond significantly to the new drug or treatment therapy. The second phase can last from several months to two years, and involves up to several hundred patients.

Phase 3 randomly compares the new treatment against the current standard of care for a specific diagnosis. Includes a larger number of participants spanning a variety of ages, ethnicities & genders, this ensures the final results will apply to larger populations.

After a Phase 3 trial, the researcher can apply for approval from the Food and Drug Administration to market and sell the product to other patients. Long term trials and population monitoring, part of Phase 4 studies, continue on for years after approval to gather information on larger and more diverse populations and demographics.

Learning To Be Your Own Best Advocate

Just like in your doctor's office, every clinical trial must meet a minimum set of standards and patient protection rules. In addition, they must be transparent and not hide anything to you as a patient. To ensure you are fully informed beforehand, trial sponsors must lay out ALL the details including specific information on research goals, therapies that will be used, testing you will undergo, known risks, possible benefits, potential side effects, time line and length of the study along with contact information for your medical team. This document is known as informed consent and your copy will serve as a good reference during the trial.

The trial will also list elements that you are responsible for and can plan for, including arranging for caregivers, transportation or overnight visits. In trials, you are given more information upfront about the care path ahead of you, giving you the power to be your own advocate. Use this information to ask questions and stay engaged with your care decisions.

One Size Doesn't Always Fit All

We have known for a long time that this phrase isn't always true when it comes to our clothing sizes, but now medical researchers are seeing that your treatment path is not necessarily the same as other patients with the same disease name, but instead perhaps determined by how your specific body works. Today's research has shown that its how your cancer, tumor or diseased cells are forming and behaving that can make a difference in whether your body gets better using a specific treatment.

Two new approaches to recruiting patients for trials have emerged as a result of this more personal approach. Known as ***basket trials*** and ***umbrella trials,*** researches are designing trials that test the effectiveness of new therapies or targeted care when everyone with the same diagnosis is not grouped together and assumed to have the same biology. Instead these trials suspect that specific techniques and new treatment options will improve overall success rates when targeted to patient groups that are based on common cellular behavior or particular genetic or molecular trait instead.

Moving into this targeted and individualized style of treatment has already shown successful outcomes with fewer side effects because treatment is catered to a patient's specific biology, or the genetic or genomic profiles in the tumor itself.

Similarly, one of the fastest growing areas of successful medicine is called immunotherapy. This is where your body's own natural defense mechanism is strengthened and then used to fight the diseased cells, instead of bringing in items that do not occur naturally in the body.

Finding a Trial Doesn't Have to Be an Individual Task

Doing any kind of medical research can be overwhelming for many patients and family members. Finding trial options and figuring out if you match the eligibility requirements for participating can take time and usually includes unfamiliar technical medical terminology. But you are not alone. Members of the healthcare community can help do some of the legwork for you, including nurses, navigators at the doctor's office, patient advocates, healthcare social workers and disease specific organizations. With many tools online, you or your family members can narrow the list from home, and discuss possible options with the trial contact, your doctor and family members.

In order to find a clinical trial for treatment you should be ready with some medical information, including your exact cancer type, stage, a list of previous treatments if any, the test results from your cancer diagnosis such as molecular biomarkers or genetic characteristics, and other medical conditions you also have. For non-treatment trials, you may need information from your family history or other risk factors.

Your doctor can also help identify any local or regional options. Clinical trials are conducted in a variety of settings including cancer clinics, doctor offices as well as larger medical centers. Look to see what's close to you, but also consider and inquire about transportation support before ruling out distant options.

If you do participate in a trial, you may be among the first to benefit from the new treatment being studied, but, regardless of your own outcome, your participation helps make a difference for future patients.

The Decisions is Yours to Make

Why patients ultimately decide to participate in a clinical trial are varied and personal like all medical decisions we make during our life.

Participating in a clinical trial involves a formal commitment to move forward that patients in standard paths may not have. Since your experience is being monitored and documented by researchers, they want to ensure your decision is understood.

When making your decision, its ok to take time to talk to others and choose based on what is right for you. Discuss options with your oncologist and the doctors you trust. It might also be a good time to get a second opinion from a new doctor that can give you a opinion with fresh eyes and share a recommendation on if you should proceed with a clinical trial based on your diagnosis and treatment history.

Following medical opinions you will want to consider your own views and talk to your family members about the possible medical and lifestyle impact of all treatment options. Share information you've learned about your options and encourage your family to ask questions as well. Consider any cost, time and logistics issues for you and your caregivers and make a plan to address so your care is uninterrupted.

Remember that even if you decide to start a trial, if you feel the need to withdraw at any point for any reason, you do have the right to change your mind. You can stop participating in a trial at any point you choose.

It May Be Good for Your Wallet

Compared to the standard treatment you would otherwise get from your doctor, there are costs associated with clinical trials. The good news is that you may not be the one paying for all of them.

As with any medical care you receive, you are responsible for payment of doctors, treatment and services received that are normal for your diagnosis. If you are insured, your health plan would help pay these charges according to your benefits, even if you were not participating in a clinical trial. This includes the standard medications to treat cancer and its side effects, doctor visits to network providers, lab tests, and imaging studies that are normal for treatment, prevention or management of your diagnosis. The Affordable Care Act (ACA) requires most insurance companies to cover costs associated with receiving standard care in the plan's network, even for those participating in a research study, and not exclude you from receiving what you would receive if not participating in a trial.

When participating in a trial, there may be other study specific items you receive, including the medications, interventions or procedures that are being tested. The study sponsor pays for these and will share the list of specific care they pay for with you in the beginning. The study may also provide stipends or reimbursement if there is travel, parking or tolls required, and to help with other costs like childcare, food, lodging or caregiver support.

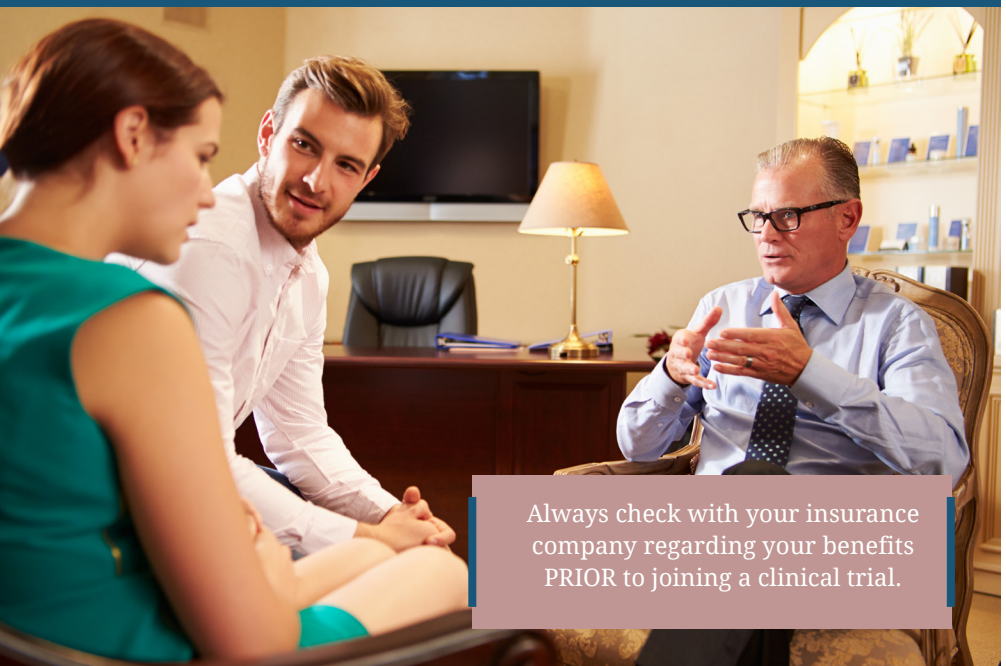
For those without insurance or with limited benefits, having the study pay for trial items reduces their own cost and provides a method of care that may have been too expensive otherwise.

However, be aware that there might be elements that neither the study nor your insurance will pay for that you should pay close attention to. For example, look closely at the list to make sure you are not expected to see doctors outside of your network, or that there are not additional lab or imaging scans that are required along the way. You should also call your insurance company to double check their coverage of items you know you'll need during the trial to prevent any surprises down the road.

The Affordable Care Act requires non-grandfathered private group and individual insurers to cover the routine costs for all phases of clinical trials intended to prevent, detect, or treat cancers and other life threatening illnesses. In order to meet the requirements, the trial must be federally funded or being conducted by an organization that is federally funded (includes academic institutions, designated cancer centers and cooperative groups); and must also be conducted under an Investigational New Drug (IND) application. In addition to the ACA, there are 39 states that have added laws that addressed insurance coverage for participating in a clinical trial.

Questions to Ask

- What are my options for taking part in a clinical trial?
- What are the eligibility requirements?
- When does the trial start? How long will the trial last?
- What is the trial studying and how does this relate to me?
- Who will be in charge of my care? Will I be able to see my own doctor or a doctor in my network?
- How often will I need to visit a physician's office?
- What tests and treatments can I expect throughout the trial?
- What are the likely side effects from the treatment? How will these possible side effects affect my daily life?
- Are there treatments to manage any side effects?
- Will I need to be at a specific facility to receive the care? If so, how often and for how long?
- Which costs will my insurance cover? What costs are paid by the study?
- Are there reimbursement options for the non-medical parts of the trial, including transportation, parking, tolls, childcare, food or other supplies?
- What will the information collected during the trial be used for? What are the research results so far for patients like me?
- Can I participate alone, or is it required that I bring a family member? What is required of my caregiver or family member?
- What support will be available for me and my caregivers during the trial? Can I talk to other people participating in the trial?
- What happens to my care after the trial is complete?
- Who can answer additional questions I might think of later?



Always check with your insurance company regarding your benefits PRIOR to joining a clinical trial.

You're Not a Guinea Pig

By the time trials are approved by the official medical agencies to start recruiting patients, there has been significant research, *frequently years of research*, that indicates that this option could possibly improve your health. Researchers have rigorously tested, observed and published medical aspects in many pre-clinical settings before bringing it to patients.

Only 16% of cancer patients report having been aware that possible matching trial options exist. Even fewer were made aware by their doctor or specialist.

Most Patients (And Doctors) Forget That It's Not Just for Treatment.

There are lots of different types of studies that are trying to improve your overall healthcare and care experience, all wrapped under the "clinical trial" name.

For example, researches may be looking to identify actions that help us prevent disease, develop easier tests that help us detect and diagnose disease faster, investigate whether there are additional things that can added alongside modern medicine to improve our quality of life or reduce side effects of today's treatment and many other advances.

Sometimes studies are simply observational in nature and are recording trends or looking at DNA or behavioral connections between patients. Some might be adding non-medical components to medical care to improve the effectiveness of medications, like stress reduction, better sleep, emotional health or complimentary techniques. Some studies also are looking at various educational tools or system processes to improve health outcomes and reduce patient frustration.

Some trials include people that are not sick, or have not been diagnosed but have family history that makes screening techniques important.

Even treatment trials may simply be testing whether an additional round or dose of the current medicine would lower your chances of the cancer returning, or if a drug approved for a similar disease would work for yours. Trials are very diverse in what they are studying.

The Practical Side of Trial Participation

In addition to making the decision to participate in a trial based on the medical reasons of your care, patients must also determine if the requirements of participating in the trial fit into their lifestyle. While every treatment and medical care option presents its own practical, financial and emotional challenges, it is important to learn as much as you can beforehand so you have time to decide your path without unexpected roadblocks.

Before you are able to finalize your enrollment into a study, the organizers will provide you with a list of the responsibilities you are expected to fulfill to ensure the trial results are captured the same for everyone. Be sure to read this closely and ask questions.

Some of the biggest challenges patients report when it comes to participating in treatment trials relate to the financial cost. Expenses may come from affording the insurance plan's out-of-pocket costs, covering any trial-related care that is not covered by insurance, additional money strain that results from out of the area travel, or spending longer time away from home and/or work.

Additionally, trials can require more from your family and the caregivers around you, including larger time commitments when taking you to treatment or doctor visits. Asking questions will help you understand what to expect.

The Family and Medical Leave Act may protect your job related to medical illness or caregiving for others, allowing extended time away from work up to 12 weeks.

What's Next? How Do I Find a Trial?

You have decided to add the possibility of a trial to your list of treatment or care options and want to look further into the benefits as part of a research study. The first step is to identify if there are any current trials that are recruiting new patients that match your medical situation.

Although there is no single source, there are web matching tools as well as organizations that can help you sort through the treatment and non-treatment trial options. When you have identified those that you meet the basic eligibility for, your doctor or the contact person for the trial can help you understand the medical terms.

While you don't need your doctor's permission to consider or engage in a trial, you will want to keep them advised of your ultimate decision so that your medical records will reflect all of the care or treatment you receive.

Some of the breast cancer specific clinical trial sites include:

BreastCancerTrials.org

Metastatic Trial Search
www.breastcancer.org/treatment/clinical_trials

Coalition of Cancer Cooperative Groups www.Cancertrialshelp.org

EmergingMed Clinical Trial Navigation www.emergingmed.com/

Metastatic Breast Cancer Network
www.mbcn.org/clinical-trial-information/

National Cancer Institute Clinical Trial Registry
www.cancer.gov/clinicaltrials

National Institute of Health
www.clinicaltrials.gov

CenterWatch
www.centerwatch.com/clinical-trials/

Triple Negative Breast Cancer Foundation
tnbcfoundation.org/clinicaltrials.htm

Trial Check
www.cancertrailshelp.org/cvancer-trial-search/

Clinical trials are not right or practical for every patient. PAF encourages you to investigate and research possible options that match your specific medical diagnosis and treatment history and make an informed decision about your care with the assistance of trained medical personnel.