color®

# Testing Innovations in Cancer

## How to evaluate and use new technologies to improve outcomes in your population

Amidst rising cancer prevalence and soaring costs, new cancer technologies and innovations are emerging to support the early detection, treatment, and surveillance of cancer.

Read this guide to understand how to evaluate these solutions for your employees and members – and to learn more about the current state of coverage, clinical and cost effectiveness, and impact on quality and outcomes.

In 2024, there will be over 2 million new cancer diagnoses in the U.S., according to the American Cancer Society.[1] As cancer incidence and the cost of cancer both continue to increase at alarming rates, so do the number of technologies that attempt to change how cancer is detected, treated, and monitored. With so many companies offering solutions to support various points of care, it can be difficult to understand how each test or service fits within the broader context of a complete, population-level approach to cancer. To truly make an impact on their population, employers need to reframe their thinking about care as a journey from health to illness and back to health. They must weigh the tradeoffs between different benefits offerings and design for comprehensive care at every stage of the cancer journey. This means:

**A** Detecting cancer at its earliest stage to structurally change outcomes and costs

**B** Optimizing treatment and care to support employees with cancer

**C** Surveillance of cancer after treatment to maximize long-term chances of survival

## Mapping Technologies to the Care Continuum*

### Early Detection

Screening for cancer to detect it at an early, treatable stage

#### Multiple cancers

- GRAIL
- ezra
- EXACT SCIENCES
- prenuvo

#### Single cancers

- Bexa
- DermTech
- Butterfly
- skinIO see more
- freenome
- DELFI
- LetsGetChecked
- GUARDANT
- teal health

### Treatment

Personalized cancer treatment and decision support through genomic profiling

- Myriad genetics
- FOUNDATION MEDICINE
- EXACT SCIENCES
- GUARDANT
- natera
- ONEOME
- TEMPUS
- 23andMe
- genesight
- RPRD DIAGNOSTICS — Right Patient | Right Drug —

### Surveillance

Monitor for cancer recurrence and progression post-treatment

- natera
- GUARDANT
- EXACT SCIENCES



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This white paper provides a framework for evaluating the many new innovations in cancer testing to help you reduce the burden of cancer on your employee population. The framework outlines:

### Purpose

Who should the test or service be used for? Does it support a small set of your population or a broader group?

### Test Performance

How well does a given test actually work at helping identify cancer? This includes considerations for tests' sensitivity (the proportion of people with cancer who correctly get a positive result from a test) and specificity (the proportion of people who don't have cancer who correctly get a negative result), as well as considerations regarding predictive value (respectively, the proportion of people with a positive or negative test result who actually have or do not have the disease).

### Regulation

Where does the test or service stand with regulators (i.e., is it FDA-approved)? What is the perspective of professional societies like the American Cancer Society and the U.S. Preventive Services Task Force when considering the test or service?

### Availability

Is the test or service accessible and available? Will it be able to reach your employees equitably? Is it covered by most insurance plans?

### Implementation Considerations

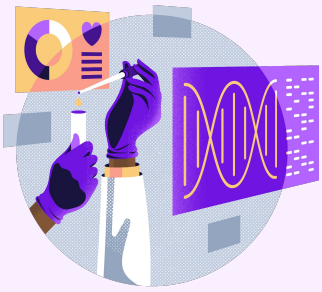
If you choose to support a specific new screening technology in your benefits plan, what is the most clinically responsible and effective way to implement it? What is the role of this new technology alongside traditional screening approaches, clinicians' remits, and other factors as part of your comprehensive cancer strategy?

Read on for our guidance on which technologies can be most impactful at each stage of the cancer journey, and the tradeoffs, costs, and benefits to weigh for each one. We're here to equip you with the information needed to make decisions that drive the best cancer outcomes in your employee population.

# Detecting cancer at its earliest stage

Guideline-based screenings, such as mammograms for breast cancer and colonoscopies for colorectal cancer, remain the gold standard for early cancer detection, having been rigorously evaluated for clinical utility, safety, cost-effectiveness, and other factors. But in the last few years, new tests and screening tools have emerged to potentially augment standard screening practices and improve access. Three of the most interesting areas of innovation in **early cancer detection** include:

1

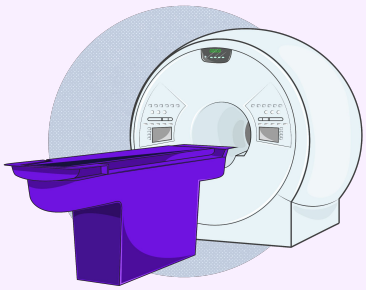


New blood tests to screen for cancer

2

Novel sample collection & mobile imaging devices

3



Comprehensive, whole-body imaging

1

## Understanding blood tests to screen for cancer

New blood tests for early cancer detection are an emerging, potential screening approach based off of a blood draw. These are not the routine blood tests that a doctor would typically order at an annual check up. These tests leverage liquid biopsy technology to detect genetic material from tumors (circulating tumor DNA) that can be found circulating in a patient's bloodstream. Professional medical societies have increasingly acknowledged the potential these tests have to identify cancer markers in the blood before symptoms appear, improving the chances for successful treatment outcomes. But none today have been embraced in professional medical guidelines.

## There are two main types of blood tests in development to screen for cancer:*

### Single-cancer early detection (SCED) tests

DELFI | freenome | GUARDANT

### Multi-cancer early detection (MCED) tests

GRAIL | EXACT SCIENCES

### Purpose

SCEDs are blood tests used to screen for one type of cancer from a single sample of blood, whereas MCEDs look for multiple types of cancer at once. These blood tests are not meant to replace standard screening tests such as mammograms for breast cancer, or colonoscopies for colorectal cancer. Rather, they can augment existing cancer screening options.

### Test Performance

There are several trials underway to better understand the ability of these tests to accurately detect cancer when it's present and to correctly determine when it's not.[2,3,4,5]

To date, SCED and MCED tests' ability to accurately detect disease have varied results across cancer types and cancer stages. While these tests are capable of detecting cancers that aren't otherwise screened for (e.g., pancreatic and ovarian cancers), they are not as good as gold-standard screenings for cancers with established screening guidelines (e.g., breast, prostate, and colorectal cancers). This is particularly true for early-stage cancers. In addition, the clinical signal of origin predictions included as part of an MCED result – which indicate where a person's cancer started – are currently incorrect about 10% of the time.[6]

### Regulation

While there are several companies working to develop MCEDs and SCEDs for lung, colorectal, and other cancers, none are currently cleared or approved by the FDA or recommended by professional guidelines.

### Availability

Currently, there are only two liquid biopsy tests commercially available for cancer screening – Grail's MCED (Galleri) and Guardant's SCED (Shield) for colorectal cancer. The Galleri test is intended for individuals 50 years of age and older, but in some cases, may be appropriate for people with certain risk factors for cancer starting at age 40. Consistent with standard colorectal cancer screening recommendations, the Shield test is intended for people 45 years of age and older at average risk for colorectal cancer.

**To decide whether or not to incorporate these new screening blood tests into your cancer solution, consider the following:**

**Test performance.** A good screening test is one that is highly sensitive and specific, meaning that it will reliably detect cancer if it's there and false positive results are rare. For a new test, it's important to compare the performance to the gold standard screening test(s). For example, Guardant's Shield test for colorectal cancer is approximately 83% sensitive and will have a false positive result ~10% of the time.[7] Stool-based colorectal cancer screening using a fecal immunochemical test (FIT) is less sensitive (~74%), but will result in fewer false positive results (~5%).[8] These performance metrics can be used to project downstream clinical needs and inform decisions about which screening test(s) are best suited for your population.

**Clinical utility.** The clinical utility of gold standard screening tests, such as stool-based tests (colorectal cancer), HPV tests (cervical cancer), and mammograms (breast cancer), have been extensively evaluated. These tests are generally effective at detecting cancer early and reducing cancer-specific mortality, which are deaths caused by cancer. However, the clinical utility of these new blood tests is still being evaluated. Trials to date have focused on test performance. But given how recently they've been developed, data on whether these tests result in a reduction in cancer deaths aren't yet available and may take years to generate.

**Cost effectiveness.** Most of these tests carry a significant price tag, often costing several hundred dollars each, and they're not covered by insurance. Especially as data on their overall benefit has yet to be defined in broad, diverse populations, it's crucial to weigh these costs against the potential benefits for your population. Pay particular attention to your proportion of average-risk members, who may benefit just as much from less expensive, traditional screening methods.

**To be implemented effectively, we believe that any program that incorporates blood tests to screen for cancer into their health plan should be supported by four components:**

**Effective risk stratification.** A health risk assessment should be used to identify high risk individuals that are both eligible for the test and most likely to benefit from taking it (i.e. over 50 years of age, not undergoing cancer treatment, not pregnant, etc.).

**Strong educational resources.** All individuals should receive education, in multiple formats, about the importance of standard screening tests and how blood-based screening tests should complement but not replace standard screenings.

**Universal pre-test counseling.** Prior to taking the test, a clinician should collect a comprehensive medical history and discuss the benefits and limitations of the test.

**End to end follow-on care.** The ability to effectively connect patients to appropriate follow-on care, not only helping to interpret and explain abnormal results through a clinician, but also supporting patients longitudinally through an often complex diagnostic workup.

2

# Understanding novel distributed screening tests

Sample collection and access to quality in-person imaging and specialist appointments are key structural barriers to cancer screening. The following technologies can remove these roadblocks by allowing cancer screening to start outside of a traditional healthcare environment:*

## Novel sample collection methods

teal health

DermTech

LetsGet Checked

skinIO™ see more

## Mobile apps and imaging devices

Bexa

Butterfly™

### Purpose

Novel sample collection devices allow individuals to collect samples independently at home, potentially reducing discomfort and facilitating a more proactive approach to health management. We've seen compelling sample collection methods introduced to screen for cervical, skin, and prostate cancers. Mobile apps and imaging devices are portable and rapid tools to screen for various cancers, such as the Bexa scan for breast cancer (mobile imaging) and Skin.io for skin cancer (mobile app). These solutions can be implemented in a wide range of settings, from community centers to health fairs to wellness events at job sites, or sometimes even used from home.

Both of these types of screenings are useful because they can help to engage individuals in your population who have significant barriers to traditional screening. Especially in underserved areas where individuals may have to travel a long way for a screening appointment, these screenings can reduce wait times and serve as a front door to care. In turn, this may increase adherence to cancer screening.

### Test Performance

The sensitivity and specificity varies significantly by screening type.

### Regulation

Some of these tests are discussed and/or recommended in professional guidelines, such as DermTech (skin cancer) and at-home PSA tests (prostate cancer). All have varying degrees of evidence and FDA approval status.

### Availability

These tests are typically available to specific populations through their employer, community events, or research studies.

**To decide whether or not to incorporate these novel distributed tests, consider the following:**

**Test performance.** Novel distributed screening tests should adhere to the established principles of a good screening test, ensuring they are both highly sensitive and specific. When these tests are incorporated as a preliminary triage step to a gold-standard screening, they should ideally be more sensitive than the conventional screening method. For instance, Bexa's breast elastography device is a sensitive tool to screen for breast masses. If someone is found to have a breast mass with the Bexa device, the mass is then assessed with an ultrasound and may be followed up with a diagnostic mammogram or other screening test. Less sensitive and specific tests could be considered when they are likely to improve uptake of the standard screen. Beyond traditional measures of test performance, factors such as safety, ease of use, and robust performance across diverse environmental conditions are critical considerations for self-administered tests. These attributes ensure that the tests are not only effective but also accessible and reliable for widespread community use.

**Clinical utility.** Distributed screening tests typically offer the advantage of being less invasive and more convenient than traditional screenings. However, many novel tests may lack long-term clinical utility data, making it difficult to evaluate their impact on clinical outcomes over time. It's important to determine whether these tests address a significant need within your population – for example, if they screen for the most common or challenging-to-detect cancers in your workforce's unique demographic. Additionally, consider the test's applicability to different segments of the population, such as its suitability for a younger audience versus current guidelines' recommendations.

**Cost effectiveness.** Depending on the technology, distributed tests may not be costly, and for that reason, may seem appealing to integrate into a comprehensive cancer solution. While some tests (such as the DermTech Pigmented Lesion Assay) are recommended by professional guidelines as a possible method of screening, others are not discussed in guidelines and should not be used to replace potentially pricier, gold-standard screenings. In the absence of a cost-effectiveness study, consider how the addition of this test impacts your clinical protocols. Will the test capture an audience that otherwise would not be screened, therefore detecting cancer earlier in more people? Or will it result in many false positives that lead to costly and/or unnecessary follow-up?

**To be implemented effectively, we believe that any program that incorporates distributed tests to screen for cancer into their health plan should achieve the following:**

**Integration with other screenings.** It's essential to consider novel distributed screening tests as one part of a larger, comprehensive cancer strategy. While they can serve as valuable tools for expanding access to screening for specific cancers, they should not be used as a replacement for standard screenings. It's also important to view these tests within the broader context of your population's health needs, which likely extends beyond a single cancer type.

**Expanded access to screening.** These tests should specifically target individuals within the employee population who face clear access barriers, making early detection more attainable for those who might otherwise miss out on screening opportunities.

**Linkage to follow-up care.** It is essential to ensure a direct link to clinical follow-up; many primary care providers may not be familiar with these distributed tests and could inadvertently reorder unnecessary tests. Strong clinical management and integration into a comprehensive strategy with a provider group specializing in cancer will enhance the efficacy and coordination of the screening process.

3

# Understanding comprehensive imaging

In recent years, whole-body MRIs and CT scans for cancer screening have garnered significant public interest and attention. However, professional societies such as the American College of Radiology and the American Academy of Family Physicians do not believe there is sufficient evidence to suggest that these tests are appropriate for screening in the absence of significant symptoms, risk factors, or a family history.*[9,10]



## Purpose

Comprehensive imaging, including whole-body MRIs and CT scans, provide detailed and holistic scans of the body. These scans can offer a highly sensitive assessment of multiple cancers at one time.

## Test Performance

While whole-body MRIs have the potential to make preventive care more efficient, they may lead to false positives or cause unnecessary anxiety and follow-up procedures after revealing a benign incidental finding.[11] In addition to false positives and incidental findings, a negative result on a comprehensive imaging test can at times offer false reassurance that cancer isn't present.

## Regulation

Currently, whole-body MRIs are not recommended by any professional medical guidelines, including the American Cancer Society, National Comprehensive Cancer Network, or the United States Preventive Services Task Force, as a screening tool for the general population.

## Availability

Whole-body MRIs without the presence of symptoms will cost the average person thousands of dollars. While targeted MRIs may be covered by health plans to screen for certain cancers, whole-body MRIs for cancer screening are generally not covered by public or private insurance. For this reason, they are not widely available. In rare cases, a whole-body MRIs may be recommended for someone with a very high likelihood of developing cancer in their lifetime.

**To decide whether or not to incorporate comprehensive imaging tests, consider the following:**

**Test performance.** Whole-body MRIs are highly sensitive tests, typically used in an oncology setting for individuals with a very high lifetime risk of cancer or to manage and monitor disease. Because they are highly sensitive, whole-body MRIs in this context can lead to overdiagnosis and incidental (non cancer-related) findings.

**Clinical utility.** If you are implementing comprehensive imaging for asymptomatic individuals as part of your cancer solution, it is important to consider the likelihood of identifying cancer and the expected rate of incidental findings in your population that will need to be managed. In a review of over 6,200 whole-body asymptomatic MRI examinations for cancer screening, 30% of participants needed additional workup. Just 1.1% of all participants screened with a whole-body MRI had a confirmed cancer.[12]

**Cost effectiveness.** The American College of Radiology currently states that "there is no documented evidence that total body screening [with an MRI] is cost-efficient" and "is concerned that such procedures will lead to the identification of numerous non-specific findings that will not ultimately improve patients' health but will result in unnecessary follow-up testing and procedures, as well as significant expense." [13]

**To be implemented effectively, integrating comprehensive imaging *to screen* for cancer should consider the following:**

**Test performance compared to the standard screen.** When implementing a supplemental test in an employer population, it's important to consider how it performs versus the gold standard. If a test that generates a lot of false positives (more than the standard screening test) is available to everyone, this can have significant implications on downstream clinical needs.

**Effective risk stratification.** Comprehensive imaging is not recommended by any professional guidelines as a population screening strategy for cancer. For that reason, employers should use caution and implement a thorough health risk assessment, reserving comprehensive imaging for individuals at the highest risk of developing cancer. This includes individuals with Li-Fraumeni syndrome (a genetic condition associated with >90% lifetime risk of developing cancer), where whole-body MRIs have demonstrated success in improving 5-year survival rates.[14]

**Pre-test counseling.** Clinicians need to help individuals weigh the benefits and limitations of comprehensive imaging, especially if the individual is asymptomatic. These tests should be presented as a nascent screening protocol, not as the gold standard, and clinicians should share all alternative cancer screening and risk management opportunities. When non-standard imaging is ordered, a clinician should first collect a comprehensive medical history and identify any symptoms or pre-existing conditions that may show up on the screen. This will avoid delays in care.

**End-to-end follow-on care.** Employers should have clinical protocols in place to support follow-up diagnostic testing, with full coverage by the health plan.

# Optimizing treatment and care

Optimizing cancer treatment through personalized care is crucial for enhancing patient outcomes and maximizing the efficacy of therapies. Tailored treatment plans based on an individual's genetic profile, tumor type, and disease characteristics can significantly reduce the occurrence of adverse side effects and improve overall survival rates. There are two main ways that cancer treatment and care can be optimized:*

## Tumor testing for treatment decisions

Myriad genetics | FOUNDATION MEDICINE | GUARDANT | EXACT SCIENCES | TEMPUS | natera

## Pharmacogenomic testing

ONEOME | 23andMe | genesight | RPRD DIAGNOSTICS

### Purpose

Tumor testing has become a cornerstone of personalized cancer medicine, guiding treatment based on the genetic profile of a tumor. By analyzing tumor DNA from blood or tissue samples (i.e., liquid and solid tumor biopsies), these tests help identify specific mutations and guide clinicians in selecting the most effective, targeted therapies. This precision approach not only enhances treatment efficacy but also minimizes potential side effects, significantly improving patient outcomes and quality of life.

Pharmacogenomic testing, often referred to as PGx testing, offers the potential to tailor cancer treatments to an individual's inherited genetic profile, rather than the unique genetic profile of a tumor. For example, if a person's genetics indicate they may not be able to process a certain type of chemotherapy, a PGx test can alert their doctor before they start treatment. They can then determine a different course of therapy that avoids known risks.[15,16] PGx testing can also inform the right dosage of medications and other therapies used to manage side effects such as nausea, headaches, and depression.[17,18]

### Regulation

FDA approval for tumor tests differs based on the type of test (liquid or solid) and its manufacturer. Some are designated by the FDA as companion diagnostics, essential for identifying patients eligible for FDA-approved therapies.

PGx tests aren't available for all cancer-related medications. The FDA regulates pharmacogenomic testing by setting guidelines for how genomic information can be used to influence drug dosing, safety, and efficacy.[19] In addition to the FDA, the Clinical Pharmacogenetics Implementation Consortium (CPIC) provides guidance about when and how pharmacogenomic results should be used to optimize treatment.[20]

### Availability

Tumor tests, including those needed for FDA-approved treatments, are covered by most public and private insurance plans.

PGx testing is widely available through direct-to-consumer and consumer-initiated platforms. However, awareness about the benefits of testing remains low, as does implementation and uptake in tertiary care centers and community oncology practices. Additionally, insurance coverage varies – some plans may cover limited testing but deny comprehensive tests.

**Tumor testing for treatment decisions should always be incorporated into standard clinical protocols when clinically appropriate. To decide whether or not to incorporate pharmacogenomic testing, consider the following:**

**Test coverage (genes and alleles).** Each pharmacogenomic test covers a different set of genes and alleles, providing different information about a person's response to medication. When choosing a pharmacogenomic test, first consider the most common health needs and medications used in your workforce to ensure the test will be relevant to your employees. Pharmacogenomic testing is sometimes offered in conjunction with hereditary cancer and cardiovascular risk genetic testing. Together, this information can provide a more comprehensive picture of risk and medication response characteristics.

## To be implemented effectively, consider the following:

**Close coordination between high-risk genetics experts and treating oncologists.** Interpreting complex pharmacogenomic test results is the first step in using them to guide treatment plans. High-risk genetics experts, including genetic counselors, should be made available to explain the implications of pharmacogenomic test results to patients and serve as consultants to clinicians managing an individual's treatment.

**Provide education and guidance to patients and clinicians.** Tools such as phone-based educational applications, short videos, and simple educational guides should be offered to patients to help understand their results and enable effective communication with clinicians about their results.

# Surveilling cancer after completing treatment

Minimal residual disease (MRD) refers to the small number of cancer cells that may remain in the body after treatment, which could potentially lead to a recurrence (either in the same location or elsewhere in the body) if undetected and left untreated. To get ahead of a recurrence, vigilant post-treatment surveillance is necessary.

Surveillance strategies can vary depending on the type of cancer and its stage. For instance, those diagnosed with lymphoma (blood cancer), a smoking-related cancer (e.g., lung), or kidney cancer are more likely to experience a recurrence and should be monitored closely.[21] Over time, the technology used to detect MRD has evolved, from biomarker testing to measure PSA (prostate cancer) and CA-125 (ovarian cancer) levels in the blood to more complex methods, like measuring circulating tumor DNA (ctDNA) from cancer cells in the blood.*

## Purpose

MRD testing, particularly through blood-based ctDNA techniques, is designed to identify traces of cancer in the blood, offering a sensitive and non-invasive surveillance tool. This is particularly true for lung, stomach, and other cancers that are challenging to regularly biopsy. This type of testing can detect recurrences at a very early stage, often before they cause symptoms. Today, MRD testing is often performed about every three months as part of standard-of-care surveillance for many blood cancers as well as breast, colorectal, lung, and other solid tumor cancers. In many cases, incorporating MRD testing into the standard practice not only enhances the accuracy of surveillance, but also provides crucial lead time for intervention, potentially improving patient outcomes.

## Test Performance

MRD tests are typically evaluated based on their ability to measure ctDNA levels in the blood and predict recurrence of a cancer. Currently, MRD testing is most advanced for blood cancer, though rapid advancements are being made for solid tumor cancers such as breast, colorectal, and lung cancers.

## Regulation

MRD tests are at different stages of regulatory approval by the FDA – some have received FDA approval and others remain laboratory-developed tests (LDTs) regulated by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA).

## Availability

MRD testing is ordered by a clinician to inform management decisions. These costs are typically included in most health plans, though coverage may vary based on the clinical indication and other patient factors.

**When clinically appropriate, as determined by test eligibility criteria, programs should regularly incorporate surveillance testing to screen for recurrence. Individuals undergoing surveillance testing should be offered MRD testing and supported in the context of a holistic survivorship care program.**

**Color's cancer care solution, built in partnership with the American Cancer Society, is a comprehensive, integrated care model that supports participants from detection through diagnosis, care, treatment, and survivorship. Through a first-of-its-kind Virtual Cancer Clinic, Color provides risk education, assessment, and management, plus accessible screenings, a nationwide clinical care network, holistic patient support, ongoing educational programming, and survivorship and mental health resources.**

To better understand how Color's Virtual Cancer Clinic can help you effectively route members to the right care, **set up a consultation** with one of our experts to learn more or reach out at **learnmore@color.com**.

color.com
831 Mitten Rd. #100
Burlingame, CA 94010

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