



GRAIL Galleri® Test Quick Reference Guide

For TRICARE West Region Providers

Key Points

- The GRAIL Galleri[®] test screens for over 50 cancer types, including cancers not detected by standard screening tests.
- The Defense Health Agency (DHA) approved this test for TRICARE patients 50 years or older with an elevated risk of cancer.
- You can submit a pre-authorization request for the test with the Referral and Authorization Management Tool. Order the test from the Galleri Get Started page.

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Introduction

This guide covers everything TRICARE providers need to know about the GRAIL Galleri® test.

What is the GRAIL Galleri® test?

The GRAIL Galleri® test is a new early cancer screening tool, allowing you to screen TRICARE patients for over 50 types of cancer with one test. These include cancer types that are prevalent among TRICARE beneficiaries, such as pancreatic cancers. The DHA approved this test for annual screenings for TRICARE patients 50 years or older with an elevated risk of cancer.

How does the test work?

The test administrator will take one blood sample from the patient. The test will then detect any cancer signals (cell-free DNA methylation patterns associated with cancer) and predict where the cancer is located. For more information, visit the <u>Galleri® Provider Frequently Asked Questions</u> page.

Note: The GRAIL Galleri® test should not be used as a substitute for diagnostic testing. Please use the test along with recommended cancer screening tools.

Why should I use the GRAIL Galleri® test for my TRICARE patients?

The GRAIL Galleri® test screens for many types of cancer and precancer that standard screening tests cannot detect. On average, the GRAIL Galleri® test can detect cancer one year before clinical diagnosis. The test's key metrics include:

- Sensitivity (accurate detection of cancer): 76.3%
- Specificity (percentage of patients who test negative): 99.5%
- Positive predictive value (likelihood of a positive test result in a patient with cancer): 43.1%
- Accuracy (accurate prediction of cancer type and location): 93.4%

Other cancer screening tests have far lower sensitivity results, such as Cologuard[®] at only 43%. Two large-scale, peer reviewed studies have verified the GRAIL Galleri[®] test: the Circulating Cell-Free Genome Atlas (CCGA) and the PATHFINDER Study.

Use your best clinical judgment when deciding if the GRAIL Galleri® test is right for your patient, as well as when interpreting test results to guide further testing and treatment.

Is the GRAIL Galleri® test FDA-approved?

No, the GRAIL Galleri® test is not currently FDA-approved. The DHA approved the test as a Laboratory Developed Test (LDT), so the test received authorization within TRICARE guidelines.

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Who should I screen using this test?

The DHA approved the GRAIL Galleri® test for annual screenings of **TRICARE** patients 50 years or older with an elevated risk of cancer. These elevated risk factors include:

- Documented military service-related exposure to occupational hazards or hazardous materials (asbestos, Agent Orange, burn pit smoke, and others)
- **Personal history of cancer** (cancer that required immediate intervention; must be at least 3 years since last treatment)
- Family history of cancer (two or more first-degree relatives)
- Obesity (BMI of 30 kg/m2 or more)
- **Smoking and vaping** if over 20 pack-years (either currently or in the past 15 years if patient quit)
- Human immunodeficiency virus (HIV)
- Previous solid organ transplant

TRICARE will only cover the GRAIL Galleri® test once in a patient's lifetime.

How do I order a GRAIL Galleri® test for a TRICARE patient?

You'll need a pre-authorization from TriWest Healthcare Alliance for approval. You must provide documentation of informed consent when submitting the pre-authorization.

Navigate to the <u>provider portal</u> and access the online referral management system to start a request. For more information on authorizations, visit the TriWest <u>TRICARE Referral and Authorization</u> <u>Guidelines</u> page.

Order a GRAIL Galleri® test on the Galleri® Get Started page.

Where can I learn more about the GRAIL Galleri® test?

Visit the Galleri® Provider Frequently Asked Questions page to learn more about the GRAIL Galleri® test.

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