

TRICARE

Patient and Provider Ordering Guide

TRICARE[®] now covers the Galleri[®] multi-cancer early detection test for beneficiaries aged 50 and older with an elevated risk for cancer.

The Galleri multi-cancer early detection test can be taken through a simple blood draw and screens for many of the deadliest cancers before they become symptomatic, including many of those with no recommended screening today.^{1,2,3} Visit [Galleri.com/50cancers](https://www.galleri.com/50cancers) to learn about what cancers the Galleri test screens for.

The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur. The Galleri test should be used in addition to recommended screening tests.

TRICARE coverage criteria

Age 50 years or older with an elevated risk of cancer, due to at least one of the following:

- Documented Military Service-related exposure to occupational hazards or hazardous materials (e.g., asbestos, Agent Orange, burn pit smoke)
- Family history of cancer in two or more first-degree relatives
- Personal history of smoking or vaping if over 20 pack-years (either currently or in the past 15 years if patient quit)
- Personal history of human immunodeficiency virus
- Personal history of solid organ transplant

If your healthcare provider determines that you may be eligible to receive the Galleri test as a covered benefit through TRICARE, your provider will submit a Prior Authorization to confirm coverage.

Prior authorization approval is subject to the individual TRICARE contractor's review.

How much will the Galleri test cost?

Contact your TRICARE contractor to determine if you have out-of-pocket costs for the Galleri test. A Prior Authorization submitted by your healthcare provider is required for coverage.

Eligibility criteria may change, and pricing is not guaranteed.

Important Safety Information: The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those age 50 or older. The test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. The Galleri test is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of the test is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment. Results should be interpreted by a healthcare provider in the context of medical history, clinical signs, and symptoms. A test result of No Cancer Signal Detected does not rule out cancer. A test result of Cancer Signal Detected requires confirmatory diagnostic evaluation by medically established procedures (e.g., imaging) to confirm cancer. If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False positive (a cancer signal detected when cancer is not present) and false negative (a cancer signal not detected when cancer is present) test results do occur. **Rx only.**

Laboratory / Test Information: The GRAIL clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. The Galleri test was developed — and its performance characteristics were determined — by GRAIL. The Galleri test has not been cleared or approved by the Food and Drug Administration. The GRAIL clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

Healthcare Provider Information

Follow the steps below to order the Galleri test for your patients as a covered benefit through TRICARE.



Who is eligible to receive the Galleri test as a TRICARE covered benefit?

TRICARE beneficiaries aged 50 and older at an elevated risk for cancer as determined by their healthcare provider.

See page 1 for examples of cancer risk factors. If the Galleri test is right for your TRICARE patient, follow the steps below to order the test. If you are affiliated with a health system, check with your health system administrator for any different ordering workflows.

1. Submit a Prior Authorization

A Prior Authorization must be submitted to the appropriate TRICARE contractor and approved before ordering a Galleri test and drawing blood (date of service). Submit a Prior Authorization through a TRICARE designated portal:

- TriWest** Availability portal: <https://tricare.triwest.com/en/provider/secure-portal/>
- Humana Military** Self-service Tool: HumanaMilitary.com/Login. Complete and upload the [LDT attestation form](#) at humanamilitary.com/provider/refsauths with the submission.
- TRICARE For Life (TFL)** Register to submit online at www.TRICARE4u.com OR fax the [authorization form](#) to **608-301-3226**
Enter your contact details (name, phone, fax, email) highlighted in the Laboratory Information section in the attached document.

Galleri test information that may be needed to complete the Prior Authorization:

- **Test name:** Galleri
- **Procedure or CPT code:** **81479**
(unlisted molecular pathology procedure)
- **Diagnosis code:** Discretion of provider
- **Lab:** GRAIL, Inc
- **NPI:** **1053089425**
- **Tax ID:** 86-3673636
- **Address:** 4001 E NC Hwy 54 Assembly Suite 1100
Durham, NC 27709
- **Phone:** 833-694-2553
- **CLIA #:** 34D2231294

2. Complete a Galleri Test Requisition Form (TRF)

Use TRF V7, visible on the bottom right of the form

- If this is your first order, start ordering online at provider.grail.com/onboarding. You could also order by submitting your TRF via fax, paper, or existing [Provider Portal account](#).
- Include the Prior Authorization number on the form
- Mark "Bill to insurance" and specify primary and secondary insurance as applicable

If you **do not** have Galleri test kits on hand

- On the TRF (V7), select YES to "Ship a specimen collection kit to this patient" and include their shipping address and email on the form.
- Fax the Cover Sheet, completed TRF (V7), Prior Authorization, and a copy of the patient ID card (if available) to: **650-999-9000** (GRAIL Customer Service fax).
- You will receive a fax confirmation after the order is reviewed and placed.

If you have Galleri test kits on hand

- Include the completed TRF (V7), Prior Authorization, and a copy of the patient ID card (if available) with the Galleri test kit for shipment back with the sample.
- If using a prior version of the TRF (V6 or earlier), include the Prior Authorization number and Secondary Insurance information in the comment box under Patient's Clinical Information.

3. The patient completes a blood draw, no fasting required

After the Prior Authorization has been approved by the patient's TRICARE contractor, a blood draw must be completed within the valid authorization window, either at your clinic or at a GRAIL partner laboratory. To schedule a blood draw (included in the cost of the test), the patient should visit Galleri.com/schedule. The sample collection kit will then be shipped to the GRAIL lab.

Reminder: Your patient is required to bring the completed TRF, Prior Authorization, a copy of their patient ID card (if available), and the Galleri test kit to their blood draw appointment.

4. Receive results, about 2 weeks after the sample is received at the GRAIL lab

Test results will be faxed to the number you provided on the TRF. Patients will also receive an email with results if they included their email on the TRF. **There are two possible test results:**

To learn more about test results, visit Galleri.com/results

✔ **No Cancer Signal Detected**

❗ **Cancer Signal Detected**

In the case of a Cancer Signal Detected result, the test will predict the most likely origin of the cancer signal, helping guide the diagnostic workup.⁴

The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. False positive and false negative results do occur.

If you are ordering the Galleri test for the first time, GRAIL will reach out to onboard you and provide educational materials about the test and ordering process.

Learn more about the Galleri test



Galleri.com/hcp



customerservice@grail.com



833-694-2553

References: 1. US Preventive Services Task Force. A,B,C grade recommendations, cancer, screenings [cited 2023 Oct 23]. https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results 2. American Cancer Society. Cancer facts & figures 2022. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html> [GRAIL, LLC. Data on file: GA-2021-0065] 3. Klein EA, Richards D, Cohn A, et al. Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set. *Ann Oncol.* 2021 Sep;32(9):1167-77. doi: 10.1016/j.annonc.2021.05.806 4. Schrag D, Beer TM, McDonnell CH, et al. Blood-based tests for multi-cancer early detection (PATHFINDER): a prospective cohort study. *Lancet.* 2023;402:1251-1260. doi: 10.1016/S0140-6736(23)01700-2

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GRAIL



TRICARE® for Life **Non-FDA Approved Laboratory Developed Test** Authorization Request Form
Must Be Approved LDTs by Center For Medicare and Medicaid Services

Register to Submit Online at www.TRICARE4u.com

-OR-

Fax to 608-301-3226 (do not send more than one patient per fax)

Direct Questions to Customer Service at 866-773-0404

Laboratory Information

Laboratory: GRAIL, Inc.

Laboratory Address: 4001 E NC 54 Hwy Assembly Suite 1100

City: DURHAM State: NC Zip Code: 27709-0001

NPI: 1053089425 Tax ID: 863673636

Contact Person: _____ **Telephone Number and Extension:** _____

Fax Number: _____ **Ordering Provider:** _____

Patient Information

Sponsor ID: _____ or DoD ID: _____

Patient Name: _____ Patient Date of Birth: _____

Patient Address: _____

City: _____ State: _____ Zip Code: _____

Will another insurance/Medicare be paying towards this service? Yes No

Name of Insurance/Benefit: _____

Start Date For This Authorization: _____

Title of Laboratory Developed Test: Galleri

ICD 10 Diagnosis Code: _____ **Description:** _____

CPT Code: 81479 Description: unlisted molecular pathology procedure

CPT Code: _____ Description: _____

CPT Code: _____ Description: _____

Required Supporting Documentation:

History & Physical (H&P) or signed progress note supporting the patient's medical condition(s) and medical necessity of the test(s) which may include family history, risk factors, symptoms, diagnoses, laboratory testing results, and/or diagnostic testing results.

Fax Cover

Fill in the blank fields below, and fax it along with the fully completed Test Requisition Form (TRF) to GRAIL Customer Service at 650-999-9000.

Date:

Number of Pages (including cover sheet):

Recipient Information

To: GRAIL Customer Service

FAX Number: 650-999-9000

Sender Information

From:

Re: Galleri Order for TRICARE Patient

FAX Number:

Phone Number:

Message:

CONFIDENTIAL INFORMATION ENCLOSED

STATEMENT OF CONFIDENTIALITY: This facsimile message contains private, privileged, and confidential information intended only for the sole use of the intended individual or entity named above. If the reader of this message is NOT the intended recipient, you are hereby notified that any review, use, dissemination, distribution, sharing, disclosure, or copying of this communication is strictly prohibited. If you are not the intended recipient, please immediately notify us by telephone at 650-771-9752 and destroy the original message. Thank you.



Test Requisition Form

ORDER ID

Expiration:

Internal Use Only

GRAIL ID

Write in the GRAIL ID above or place the TRF label here

SPECIMEN INFORMATION

Specimen Requirements:

Two 10mL Whole Blood, cfDNA Streck BCT® Blood Collection Tubes.

Collection Date (MM/DD/YYYY)

Time (24-hour)

Collection date and time input fields

Galleri® is a multi-cancer screening test and is recommended for use in adults with an elevated risk of cancer such as those age 50 years and older. The use of the Galleri test is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

PATIENT INFORMATION

Patient information fields: First Name, MI, Last Name, Date of birth, Sex, MRN / Other ID, Street Address, City, State, ZIP Code, Phone Number, Email address, Ship a specimen collection kit to this Patient?

PATIENT'S CLINICAL INFORMATION

Clinical information fields: ICD-10 codes, Check if applicable (Solid organ transplant, Bone marrow transplant, Cancer survivor, Cancer suspicion with Signs or Symptoms, Active cancer with or without treatment), Comments, Patient Clinical History (Optional), Risk Factors for Cancer, Prior History of Cancer, Family History of Cancer

PROVIDER INFORMATION

Provider information fields: Ordering Provider's NPI, GRAIL Account ID, Ordering Provider's First Name, Ordering Provider's Last Name, Clinic / Hospital Location Name, Street Address, City, State, ZIP Code, Phone Number, Fax Number, Email Address

Provider attestation

I attest that the patient has been informed about the purpose and limitations of Galleri, and use of their sample and health information. I obtained from the patient authorization for the: performance and billing of Galleri, and the disclosure to and indefinite retention and use by GRAIL, Inc. (GRAIL) and any third parties of the patient's de-identified sample, health information, and test result for research, product development, and quality-related purposes. I certify the following: I am authorized to order this test (or was delegated authority by an authorized ordering healthcare provider); and the test is medically necessary for, and the result will be used in, the patient's care. I agree to provide to GRAIL all patient information necessary for billing, and any related clinical follow-up information for product-or quality-related purposes.

In addition, I attest that the patient has been informed of the following:

- 1 If Galleri is billed to the patient's health insurer or plan, it may not be covered. The patient may be responsible for any amounts not paid by the plan and by submitting patient's credit card information on this form, the patient authorizes GRAIL to charge their credit card for Galleri.
2 If the patient does not want their leftover de-identified sample used as described above, the patient may ask for sample destruction by writing to the GRAIL Customer Service Department within 60 days after the test results issuance.
3 GRAIL may share test results and patient information with the insurer or plan, and the benefits will be made payable to GRAIL.

BILLING INFORMATION (Select appropriate bill type and provide required information)

Bill to Clinic/Employer/Other. If Employer or Other, indicate the Employer/Partnership Program below. Employer/Partnership Program (if applicable)

Bill to Health Insurance. If selecting this option, attach front and back copy of the insurance card(s).

Primary Insurance Information and Secondary Insurance Information (if applicable). Fields include Insurance Company, Policy Number / Subscriber ID, Group ID, Prior Authorization Code (if required), Relationship to Patient, Policyholder's First Name, Policyholder's Last Name, Date of Birth (MM/DD/YYYY)

Bill to Patient (Self-pay). Include the patient's email in the Patient Information section above.

Patient's Credit Card Information

Credit card information fields: Cardholder's First Name, Cardholder's Last Name, Credit Card Number (Amex, MC, Visa, Discover), Expiration (MM/YY) CVV, ZIP Code

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Email: customerservice@grail.com
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