

# 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, as determined by your healthcare provider.

The Galleri multi-cancer early detection test can be taken annually 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.<sup>1,2,3</sup> Visit <u>Galleri.com/50cancers</u> 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 includes:

• Age 50 years or older, AND

Risk factors in addition to age:

- Personal history of cancer
- Family history of cancer (first degree relatives or multiple remote relatives)
- Diabetes
- Obesity
- Smoking and vaping if history matches low dose CT criteria
  - o Note: Learn more about who qualifies under the low dose CT criteria at the <u>VA's Screening for Lung</u> Cancer page.
- Genetic predisposition toward cancer (as shown through genetic testing)
- Exposure to cancerous occupational or environmental hazards, such as burn pit smoke, asbestos, Agent Orange, and more.
  - o Note: Learn more about occupational or environmental exposures at the <u>VA's Military Exposures page</u>.
- Certain autoimmune-related inflammatory conditions, such as inflammatory bowel disease (IBD), asthma, or other inflammatory diseases
- Certain non-autoimmune-related chronic inflammatory conditions, such as cirrhosis, chronic hepatitis B and C, or other inflammatory diseases
- Certain primary or viral immunodeficiencies, such as HIV, HPV, or other immunodeficiencies
- Previous solid organ transplant

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.

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.

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.

#### **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:

- a. TriWest Availity portal: https://tricare.triwest.com/en/provider/secure-portal/
- b. Humana Military Self-service Tool: Humana Military.com/Login. Complete and upload the GRAIL Galleri test attestation form at humanamilitary.com/provider/refsauths with the submission.
- c. 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

- Include the Prior Authorization number on the form
- · Mark "Bill to insurance" and specify primary and secondary insurance as applicable
- The TRF can be submitted via fax, paper, or provider portal

#### 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

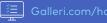
Cancer Signal Detected

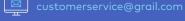
In the case of a Cancer Signal Detected result, the test will predict the most likely origin of the cancer signal, helping guide the diagnostic workup.4

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







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







# 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:					
Laboratory Address:					
City:		State: _		Zip Code:	
NPI:	Tax ID:				
Contact Person:	Telephone Nu	umber and	Extension		
Fax Number:	Ordering Provider:				
	Patient Information	on			
Sponsor ID:	or DoD ID:				
Patient Name:		Pa	tient Date	of Birth:	
Patient Address:					
City:		_State:		_ Zip Code:	
Will another insurance/Medicare be pa	ying towards this service?	Yes	No		
Name of Insurance/Benefit:					
Start Date For This Authorization:					
Title of Laboratory Developed Test:					
ICD 10 Diagnosis Code:	Description:				
CPT Code:	Description:				
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:	
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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.



ORDER ID	GRAIL ID
Expiration:	
Internal Use Only	Write in the GRAIL ID above or place the TRF label here

Test	Req	uisition	Form
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SPECIMEN INFORMATION  Specimen Requirements: Two 10mL Whole Blood, cfDNA Streck BCT* Blood Collection Tubes.  Collection Date (MM/DD/YYYY) Time (24-hour)	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'S CLINICAL INFORMATION				
Patient's First Name  MI Patient's Last Name  Date of birth (MM/DD/YYYY) Sex Assigned at Birth MRN / Other ID  Male Female	ICD-10 codes  1				
Street Address  City State ZIP Code	Check if applicable (for information purpose only)  Cancer survivor  Cancer suspicion with Signs or Symptoms  Active cancer with or without treatment				
Phone Number  Ship a specimen collection kit to this Patient?  Yes Yes, to a different address (add to the comments)  Email address	Comments  Family History of Cancer Cancer type and relationship: hereditary cancer syndrome				
PROVIDER INFORMATION					
Ordering Provider's NPI (first-time order only)  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  BILLING INFORMATION (Select appropriate bill type and provide required informatio  Bill to Clinic/Employer/Other If Employer or Other, indicate the Employer/Partnersh					
Employer/Partnership Program (if applicable)					
Bill to Health Insurance If selecting this option, attach front and back copy of the ins	wood code				
	` '				
Primary Insurance Information  Insurance Company Policy Number / Subscriber ID	Group ID Prior Authorization Code (if required)				
Relationship to Patient  Self Spouse Other  Other	Policyholder's Last Name  Date of Birth (MM/DD/YYYY)				
Seir Spouse Other  Secondary Insurance Information (if applicable)					
Insurance Company Policy Number / Subscriber ID	Group ID				
Relationship to Patient Policyholder's First Name	Policyholder's Last Name  Date of Birth (MM/DD/YYYY)				
Self Spouse Other  Bill to Patient (Self-pay) Include the patient's email in the Patient Information section above.					
Patient's Credit Card Information  Cardholder's First Name  Cardholder's Last Name	© 2021-2025 GRAIL, Inc. Galleri® is a trademark of GRAIL, Inc. All rights reserved. CLAB-FRM-0017 V7.0				
Credit Card Number (Amex, MC, Visa, Discover) Expiration (MM/YY) CVV ZIP	Tel: 833-MY-GALLERI (833-694-2553)  Fax: 650-999-9000  Email: customerservice@grail.com				