SECURE HEALTH

FAX - TIME SENSITIVE

PLEASE RETURN TO SECURE HEALTH FAX: +1 801-509-6879

To:
Fax:
Phone:
Date:
Subject:
Comments: PATIENT REQUESTED

Your patient _____ , is requesting a genetic cancer test due to concerns they have about hereditary cancer that they have had or has been in their family. Secure Health would like to include you in the process because you are the patients primary care physician and can implement the results of the test into the patient's existing care plan. **Please sign the attached requisition form, the physician authorization form, and the certificate of medical necessity. The results will be sent via fax or via online portal, depending on preference.**

Also, please note that the attached ICD-10 codes are typically associated with medical necessity for hereditary cancer screenings, but do not guarantee coverage for any genetic test. Providers are NOT required to use the attached examples. Secure Health and all associated companies do require ICD-10 codes that are:

1. Patient specific
2. Prove the medical necessity to support testing
3. Are billable to the highest specificity

Samples that are received without proper ICD-10 coding will be held for 30 days. After this period, if the correct ICD-10 codes are not included, the sample will be destroyed.

With any questions, please contact Secure Health at (801) 477-0474

Laboratory Request

ATCG
Advanced Testing in Clinical Genetics

Shih-Jwo Huang, M.D., Ph.D.
Laboratory Director
CLIA # 05D2104354

Tel 949 393 5600 | Fax 888 859 4350 | 18 Technology Drive, Suite 107 | Irvine, CA 92618

AFFIXED LABEL PT 1

SPECIMEN INFORMATION

DATE COLLECTED / / TIME COLLECTED : AM PM

☐ Swabs rubbed firmly in each cheek and under the gum

Initial of person collecting sample _____

SPECIMEN ID NUMBER

TEST REQUISITION

Patient Information

Patient Last Name

Patient First Name, Middle Initial

Gender ☐ M ☐ F

☐ **Uninsured Patient**

Patient Social Security Number — —

Date of Birth / /

Date of Injury / /

If Workers' Comp

Patient Work Phone - -

Ext.

Patient Home Phone - -

Patient Cell Phone - -

Race
☐ African American ☐ Asian
☐ Caucasian ☐ Hispanic
☐ Other: _____

Practice Information

Requesting Provider _____

Billing Information

BILL TO: ☐ Insurance ☐ Medicaid ☐ Self-Pay ☐ Medicare*#: _____

**When ordering tests for which Medicare reimbursement will be sought, physicians (or other individuals authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient, rather than for screening purposes.*

PRIMARY INSURANCE *(Attach front & back copy of card)*
Responsible Party/Policy Holder _____ Relation _____
I.D. or Policy # _____ Group # _____

SECONDARY INSURANCE *(Attach front & back copy of card)*
Responsible Party/Policy Holder _____ Relation _____
I.D. or Policy # _____ Group # _____

Diagnosis Code(s)

REQUIRED

PLEASE COMPLETE ALL GREEN HIGHLIGHTED SECTIONS.

HISTORY OF CANCER

Personal History	Family History

ORDER TESTS

Tests Requested

☐ **Full Focus Cancer Gene Panel - 30 Genes**
ATM, AXIN2, BARD1, BRIP1, NBN, CHEK2, GREM1, HOXB13, MRE11, POLD1, POLE, RAD50, RAD51C, RAD51D, BRCA1, BRCA2, EPCAM, MLH1, MSH2, MSH6, MUTYH, APC, CDH1, STK11, BMPR1A, PTEN, SMAD4, PALB2, PMS2

Patient's Consent

I, the undersigning request and authorize ATCG Laboratory to perform the tests requested above on the sample(s) provided by me. ATCG Laboratory also has my permission to outsource the processing of sample(s) at their discretion. My signature below acknowledges that I have been informed of the benefits and limitations of the test(s) and that they have been explained to my satisfaction by a qualified healthcare professional.

I authorize ATCG Laboratory to bill my insurance company directly and to receive payment from them on my behalf. I further authorize my insurance company to pay ATCG Laboratory directly for services rendered. I acknowledge that I am ultimately responsible for payment of my account and any and all charges associated with its collection.

I authorize ATCG Laboratory or their designee to appeal on my behalf in the event of an underpayment or denial by my insurance carrier and to provide the information and actions necessary to reverse the denial and receive reimbursement for the unpaid claim.* This authorization is to remain valid until the charges for the orders on this form are paid in full.

By signing below, I certify that I provided my unadulterated specimen(s) to the collector to be analyzed; that the information provided on this form and on the label affixed to each specimen is correct; and each specimen to be tested was sealed in my presence. I acknowledge that the laboratory has my permission to release my results directly to the treating physician or facility. I allow the release of any medical information necessary to process the claim and I acknowledge that ATCG Laboratory may be an out of network provider with my insurer. I further agree that should my insurance provider send payment(s) directly to me that I will endorse the insurance check(s) and forward it to ATCG Laboratory within 30 days. I understand that failure to do so may result in my account being forwarded to collections and reported to a credit bureau.

**ATCG Laboratory and/or designee are not obligated to perform this appeal on my behalf.*

Patient Signature: _____ *Date:* _____

Physician/Authorizing Medical Professional's Signature

Physician Signature: _____ *Date:* _____

Follow instructions in the collection kit to obtain and ship samples. To avoid a delay in sample processing, include photocopy of insurance card(s) (front and back), and a copy of this form in the pre-paid shipping envelope included in the collection kit. NOTE: Sample cannot be processed without all necessary information.

ATCG LABORATORY COPY – WHITE I PHYSICIAN COPY – PINK

Advanced Testing in Clinical Genetics

Date: _____

Provider Practice Information

Practice Name: _____

Address: _____

City/State/Zip: _____

Phone: _____

Fax: _____

Acknowledgement

I authorize ATCG to perform requested laboratory tests on my patients from my facility as directed on my signed orders at their primary site or any of their affiliated laboratories. I understand that it is my responsibility to determine the Medical Necessity of each / all test(s) requested. I certify that compliance with my patients / beneficiary's insurance(s) are in place, including records that reflect the need for the test(s) and document the order of the test(s). These records will be provided upon request. Further, I authorize and instruct ATCG to provide patient lab result report access online, sending account access to the listed practice contact. I understand that other delivery methods may be initiated by contacting ATCG. I understand that ATCG requisitions are to be submitted to ATCG only and that Bill Clinic invoices are to be paid on receipt.

First Name	Last Name	Title	NPI	Provider Signature

Advanced Testing in Clinical Genetics

18 Technology Drive, Suite 107, Irvine, CA 92618

CLIA# 05D2104354 Medical Director: Dr. Shih-Jwo Huang

Telephone: 888-324-6360

HEREDITARY CANCER GENETIC TESTING LETTER OF MEDICAL NECESSITY

Date of Service: _____

Patient Name: _____

Patient Date of Birth: _____

ICD-10 Diagnosis Codes: _____

Dear Claim Specialist:

Cancer is a very serious medical issue and is a leading cause of death. The purpose of this letter is to document medical necessity for hereditary cancer genetic testing for my patient so that I will receive the test results in order to pursue care for my patient and to request full coverage of my patient's DNA-based hereditary cancer diagnostic test.

Through medical discovery and human genome sequencing, the medical community has isolated that mutations in genetic coding causes hereditary cancer. Hereditary cancer is caused by gene penetrant (hereditary) cancer predisposition syndromes. In 1994, the first cancer identified and isolated with hereditary genetic linkage was breast cancer. Since 1994, 11 additional cancers have been identified and isolated with hereditary genetic linkage. These 11 additional cancers are ovarian, endometrial, prostate, colorectal, pancreatic, endocrine, renal, brain, leukemia, lymphoma, and melanoma. Furthermore, gene mutations also increase the lifetime risk for certain cancers such as colorectal, sarcomas, brain, leukemia, gastric, thyroid, and prostate. These 12 hereditary cancers are sub-classified as over 50 different hereditary cancer predisposition syndromes. [1] Evaluating a patient's personal and family history is a standard of care and a major part of hereditary cancer risk assessment. This patient presents with an atypical personal and/or familial history of cancer. Without the ability to access patient specific genetic data, which ultimately provides guidance as to whether or not my patient should be subjected to increased monitoring/management techniques, I may be unable to provide this patient with advice on adequate levels of care.

There are over 240 unique known cancer genes.[2] At present, medically accepted estimates of certain cancer-related gene mutations and associated risks for the major hereditary cancers are: up to 87% risk for breast cancer for individuals with *BRCA* mutations; up to 44% risk for second cancer for individuals with *BRCA* mutations; up to 60% risk for serous ovarian carcinoma for individuals with *BRCA* mutations; up to 10% risk for endometrial cancer for individuals with *BRCA*; up to 90% risk for colon cancer for individuals with identified polyps with *BRCA* mutations; up to 9% risk for colon cancer for individuals without identified polyps with *BRCA* mutations; up to 50% risk for breast cancer for individuals with *PTEN* mutations; up to 10% risk for thyroid cancer for individuals with *PTEN* mutations; up to 10% risk for endometrial cancer for individuals with *PTEN* mutations; up to 35% risk for renal cell carcinoma for individuals with *PTEN* mutations; up to 90% risk for colon cancer for individuals with identified polyps with *PTEN* mutations; up to 9% risk for colon cancer for individuals without identified polyps with *PTEN* mutations; up to 80% for colorectal cancer for individuals with Lynch syndrome; up to 90% for individuals with Lynch syndrome have *MLH1, MSH2, MSH6*, and *PMS2* mutations; up to 60% endometrial cancer for individuals with lynch syndrome; up to 52% risk for breast cancer (lobular) for individuals with *CDH1* mutations; up to 83% risk for diffuse gastric cancer for individuals with *CDH1* mutations; up to 20% risk for breast cancer for individuals with *CHEK2* mutations; up to 20% risk for breast cancer for individuals with *ATM* mutations; and up to 10% risk for ovarian cancer for individuals with *RAD51C, RAD51D* and *BRIP1* mutations. Additionally, other gene mutations linked to hereditary cancers include: *BMPR1A*-associated Juvenile Polyposis; Li-Fraumeni; Multiple Endocrine Neoplasia, Type 1 (*MEN1*); Multiple Endocrine Neoplasia, Type 2 (*MEN2*); *MUTYH*-associated Polyposis; *PALB2*-associated

Hereditary Cancer; Peutz-Jeghers; *SDHA*-associated Hereditary Paraganglioma and Pheochromocytoma; *SDHB*-associated Hereditary Paraganglioma and Pheochromocytoma; *SDHC*-associated Hereditary Paraganglioma and Pheochromocytoma; *SMAD4*-associated Juvenile Polyposis; and Von Hippel Lindau. [3] Significant aspects of my patient's personal and / or family medical history suggest a reasonable probability of one or more hereditary cancer(s) and / or cancer syndromes.

Clinical features of many hereditary cancer syndromes overlap and there is also a reasonable probability of detecting one or more genetic mutation(s) in my patient. Therefore, I have ordered a single comprehensive hereditary cancer genetic test as an efficient and effective way to analyze the multiple genes associated with hereditary cancer conditions. The test may analyze up to 33 genes (of the over 240 unique known cancer genes) associated with hereditary cancer (listed alphabetically) that have suspected low, medium or high penetrance for my patient:
APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM, FH, FLCN, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, RINT1, SDHB, SMAD4, STK11, TP53, VHL, XRCC2.

A positive test result would confirm a genetic diagnosis and / or risk in my patient, and would ensure my patient is being managed appropriately. An aggressive approach to medical management is necessary for my patient if identified as having a genetic mutation. Test results are important in reducing cancer risk and promoting early cancer detection. A positive result would indicate that my patient has an inherited predisposition to cancer and could help guide treatment strategies and allow for surveillance of associated organ systems known to be of increased risk for cancer.

The successive steps with my patient would be specific to the genetic mutation, degree of penetrance, and potential cancer type. Specific actions may include: utilization of appropriate guidelines (i.e., including but not limited to National Comprehensive Cancer Center Clinical Practice Guidelines in Oncology) to help guide decisions toward possible preventative measures; referral to a specialist such as an oncologist, surgeon, geneticist, or other; increased screening(s) including self-examinations, clinical examinations, ultrasound, and / or MRI (specific screening recommendations are dependent on the gene and hereditary cancer predisposition syndrome implicated); if prostate cancer, prostate cancer screening (PSA and DRE); if thyroid, thyroid ultrasound and exam; if gastric or other, more frequent colonoscopy; avoidance of radiation treatment when possible; consideration of MRI-based screening/technologies; specific pathway of genes to target with the help of potential chemotherapeutic treatment; other genetic mutation specific step-wise strategies; other cancer specific step-wise algorithms of care; provide an answer to the family about the underlying cause of my patient's condition and prevents the need for further rounds of expensive and / or painful testing; and isolate the underlying genetic cause allows for accurate family counseling and more precise estimation of recurrence risks for family members thus allowing family members to make informed, efficient and effective choices.

Fortunately screening and early diagnosis of cancer is proven to extend life expectancy, patient and family quality of life, and proven treatment algorithms cost effectively manage the disease treatment. There are multiple government agencies, medical societies, healthcare regulators, and insurance plans that mandate and / or embrace hereditary cancer genetic testing. Below you will find prominent medically accepted evidence-based guidelines, governmental agencies and other major insurance plans' justification for the medical necessity of hereditary cancer genetic screening/testing:

1) **Medical Guidelines**
   a) National Comprehensive Cancer Network ® Genetic/Familial High-Risk Assessment: Colorectal, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines ®) Version 2.2016. [4]
   b) American Society of Clinical Oncology recommends that genetic testing be offered to individuals with suspected inherited cancer risk in which test results will aid in medical management decision-making. ASCO Policy Statement Update: genetic testing for cancer susceptibility. [5]
   c) American Academy of Family Physicians Summary of Recommendations for Clinical Preventive Services; The AAFP Recommendations for Genetic and Genomic Tests is provided to aid members their delivery of evidence-based practices to their patients; recommendations for hereditary genetic cancer testing. [6]
   d) The American College of Gastroenterology Clinical Guideline: Genetic Testing and Management of Hereditary Gastrointestinal Cancer Syndromes. [7]
   e) American Gastroenterological Association Medical Position Statement: Hereditary colorectal cancer and genetic testing; recommendations for hereditary genetic cancer testing. [8]
   f) Hereditary diffuse gastric cancer: updated consensus guidelines for clinical management and directions for future research; International Gastric Cancer Linkage Consortium Consensus Guidelines 2010; recommendations for

hereditary genetic cancer testing. [9]

g) Medullary Thyroid Cancer: Management Guidelines of the American Thyroid Association; recommendations for hereditary genetic cancer testing. [10]

The genes in the test are warranted to identify the risk for cancer and / or detect cancer early, and to reduce morbidity and mortality. This genetic testing will help estimate my patient's risk to develop (and potentially die of) cancer. It will also directly impact my patient's medical management.

The test will take at least ten to twelve weeks for completion. Therefore, we are requesting that the authorization remain valid for at least 180 days. I request your written, timely response to the laboratory, given the importance of this matter. Thank you for your time.

Best regards,

Provider Name _____

Ordering Clinician Signature: _____Date_____
(MD/DO, Clinical Nurse Specialist, Nurse-Midwives, Nurse Practitioner, Physician Assistant, Genetic Counselor*)

* Clinician prescribing requirements vary by state

1.National Cancer Institute at the National Institutes of Health http://www.cancer.gov/about-cancer/causes-prevention/genetics/genetic-testing-fact-sheet
Atlas of Genetics and Cytogenetics in Oncology and Hematology http://atlasgeneticsoncology.org

[1] National Cancer Institute at the National Institutes of Health www.cancer.gov, Susan G. Komen ww5.komen.org, and the Baylor Human Genome Sequencing Center www.bcm.edu.

[2] Source: NCCN https://www.nccn.org/professionals/physician_gls/f_guidelines_nojava.asp

[3] Source ASCO https://www.asco.org and J Clin Oncol 2003;21[12]:2397-2406

[4] http://www.aafp.org/dam/AAFP/documents/patient_care/clinical_recommendations/cps-recommendations.pdf

[5] http://gi.org/wp-content/uploads/2015/02/ACG_Guideline_Hereditary-Gastrointestinal-Cancer-Syndromes_February_2015.pdf

[8] https://www.med.upenn.edu/gastro/documents/AGApositionstatementhereditarycoloncancertesting.pdf

[9] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2991043/

[10] http://www.thyca.org/download/document/280/MTCguidelines.pdf

[11] http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/