IntelligeneCG
Cancer Genomics

Enrollment/Requisition/Prior Authorization Form
Prosigna Patient Support

prosigna® patient support

Fax: 877-515-8968
Phone: 855-477-67-4462 (855-4PROSIGNA)

SECTION 1

To view our Billing and Coding Guide visit out website at **www.prosigna.com**

PROGRAMS AND SERVICES

- ☐ Insurance Verification, Prior Authorization, Prior Authorization or Appeals Support (complete sections 1 and 2)
- ☐ Free Product Assistance/Patient Assistance Program: PAP (complete sections 1, 2 and 3)
- ☐ Product Replacement Program: PRP (complete sections 1, 2 and 3)
- ☐ Expedited Review Required for Prior Authorization and Appeals

PATIENT INFORMATION ☐ Attached

Patient name:
Patient DOB:
Address:
City: State: Zip:
Email:
Home phone:
Work/cell phone:

HEALTH INSURANCE INFORMATION ☐ Attached

Primary insurance name:
Policy/Group #:
Phone:
Policy holder's name:
DOB: Relationship:
Payer/provider ID #:

Secondary insurance name:
Policy/Group #:
Phone:
Policy holder's name:
DOB: Relationship:
Payer/provider ID #:

Tertiary insurance name:
Policy/Group #:
Phone:
Policy holder's name:
DOB: Relationship:
Payer/provider ID #:

PATIENT MEDICAL INFORMATION ☐ Attached

Please provide the ICD10 diagnostic code:
Tumor Size: ☐ ≤ 2cm ☐ > 2 cm
Location of Patient's Tissue:
Required Pathology Report Attached ☐ YES
Previous treatment:
☐ None ☐ Hormone therapy ☐ Radiation
☐ Surgery ☐ Other
Clinical TNM Stage:
☐ 0 ☐ I* ☐ IIA* ☐ IIB* ☐ IIIA
☐ IIIB ☐ IIIC ☐ IV
HER2 positive? ☐ Yes ☐ No*
ER/PR status? ☐ Positive* ☐ Negative
Nodal status? ☐ Positive* ☐ Negative*
Menopausal status: ☐ Pre ☐ Peri ☐ Post*

PHYSICIAN/PROVIDER INFORMATION ☐ Attached

Person of contact:
Phone:
Email:
Physician name:
State Lic #: PTAN:
Name of group/hospital:
Tax ID #: NPI:
Mailing address:
City: State: Zip:
Phone: Fax:

Preferred laboratory for Prosigna testing:
IntelligeneCG
10900 S Clay Blvd, Suite 1400
Olathe, KS 66061
Phone: 913-258-2300

SERVICE OPTIONS

- ☐ I want IntelligeneCG to request the specimen. (COMPLETE the information below.)
- ☐ Specimen enclosed. (Refer to page 3 for instructions/tissue requirements)

Location of Tissue Specimen : Specimen ID:
Archive Retrieval Date: Phone: Fax:

SECTION 2

PROVIDER'S CERTIFICATION

By signing below, I certify that:
(a) the Prosigna Assay is medically necessary; **(b)** I have received any necessary authorization to release the information in this form and other protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 [HIPAA] and implementing regulations) to the Nanostring Technologies, Inc. Prosigna Patient Support Program (the "Program") and contractors administering the Program for the purpose of seeking reimbursement and assisting in initiating the evaluation of the patient's eligibility for the Program; **(c)** I have not received, and will not in the future seek, any payment from the patient or any third party payor for the free Prosigna test that is being provided for use for this patient or being replaced under the Program; and **(d)** I appoint the Program to convey on my behalf to the laboratory chosen by the above-named patient the prescription described herein.

I agree to comply with the program guidelines as established by NanoString and understand that NanoString, at its sole and absolute discretion, reserves the right to modify or discontinue the Program at any time and to verify the accuracy of the information submitted.

PROVIDER'S SIGNATURE

(Signature required; this form cannot be processed without an original or stamped signature.)

Last name: _____ First name: _____ Date: _____

Signature: _____

SECTION 3 — Complete only if applying for Patient Assistance Program and/or Product Replacement Program

PATIENT'S CERTIFICATION

I certify that the information about me provided in this form is true and correct to the best of my knowledge.
I understand that the Prosigna Patient Support Program (the "Program") includes programs and services, some of which are available only to patients who do not have insurance coverage for Prosigna. I understand that if I do not have insurance coverage I may need to enroll in the Patient Assistance or Product Replacement Programs and may be required to submit income verification documents to the Program for my household for purposes of determining my eligibility for the Program or to verbally confirm by phone to a Program representative the income information provided in this application.

Complete only if applying for Patient Assistance Program and/or Product Replacement Program:

U.S. Resident: ☐ Yes ☐ No Annual household income: _____ Number of people in your household: _____

PATIENT'S SIGNATURE

(Certification of patient can be provided by either an original signature or by verbal confirmation to a Program representative by phone.)

Last name: _____ First name: _____ Date: _____

Signature: _____

The Prosigna Breast Cancer Prognostic Gene Signature Assay Intended Use

In the U.S., the Prosigna Assay is indicated in female breast cancer patients who have undergone surgery in conjunction with loco-regional treatment consistent with standard of care, either as:

(1) a prognostic indicator for distant recurrence-free survival at 10 years in postmenopausal women with HR+, lymph node-negative, Stage I or II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors or **(2)** a prognostic indicator for distant recurrence-free survival at 10 years in postmenopausal women with HR+, lymph node-positive (1-3 nodes), Stage II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors. The device is not intended for patients with 4 or more positive nodes.

INSTRUCTIONS FOR USE

The enrollment form should be completed and submitted for all insured and uninsured patients who may need assistance.

Please attach the following:

- If your claim or prior authorization submission has been denied, include copies of the claims or prior authorization requests and denials of such claims and appeals

SECTION 4

TISSUE REQUIREMENTS AND PROCEDURES

1. GENERAL ASSAY CONSIDERATIONS

1.1 The assay is intended for use only on formalin-fixed paraffin embedded (FFPE) breast cancer tissue specimens from surgical resection; it is not intended for use on fresh, frozen or non-breast cancer tissue.

1.2 The tumor surface area (mm^2) of a patient's primary tumor, tumor cellularity (%) and nodal status are required to perform the assay.

2. SPECIMEN COLLECTION - Tissue Specimen Requirements and Pathology Review

2.1 The Prosigna Breast Cancer Prognostic Gene Signature Assay should be performed on a formalin-fixed, paraffin-embedded (FFPE) hormonereceptor positive breast tumor tissue specimen that is further specified by a pathologist as one of the following types of invasive breast carcinoma:

a. Invasive ductal carcinoma
b. Invasive lobular carcinoma
c. Invasive carcinoma with ductal and lobular features ("mixed type carcinoma")
d. No special type (NST) or not otherwise specified (NOS)

2.2 A pathologist should select the FFPE tumor block with the greatest area of viable invasive breast carcinoma for this test.

2.3 The test requires unstained slide mounted tissue sections for processing and a corresponding H&E stained slide from the FFPE tumor block.

2.4 It is recommended that tissue sections for assay processing are cut contiguous to the tissue section cut for H&E staining to ensure that the tumor area identified on the H&E stained slide is representative of the tumor area on the unstained slides.

2.5 A pathologist must circle the region of viable invasive breast carcinoma on the H&E slide, excluding surrounding non-tumor tissue.

2.6 A pathologist or trained laboratory technician must estimate the tumor cellularity and tumor surface area within the circled area of the H&E stained slide.

a. The tumor cellularity percentage on the H&E stained slide must be ≥ 10%*
b. The circled tumor surface area on the H&E stained slide must be ≥ 4 mm^2.

**Note that tumor cellularity percentage refers to the percentage of viable tumor cells within the circled tumor area.*

2.7 A total tumor surface area of greater than 100 mm^2 is recommended as an input for the test. The following table illustrates the number of slides recommended based on the measured tumor surface area on the H&E stained slide.

2.8 If the tissue review process shows that the tumor block has insufficient tumor area or insufficient tumor cellularity, then a different block from the same tumor may be assessed. If there are no FFPE blocks that contain sufficient tumor tissue, then the Prosigna Assay should not be run. Please note that for tumors with less than 20 mm^2 surface area, it is more likely that RNA input requirements will not be met.

TABLE 1. Recommended slide requirements based on tumor surface area.

Measured Tumor Surface Area on H&E Stained Slide (mm^2)	Number of Unstained Slides
4-19	6
20-99	3
≥ 100	1

To be provided by a pathologist or trained laboratory technician

FFPE Block/ Slide ID	Tumor Surface Area (mm^2)	Tumor Cellularity (%)	Number of positive nodes	Gross Tumor Size (cm)	Number of Tissue Sections Required	Number of Tissue Sections Provided

For IntelligeneCG Laboratory Use

REQUIRED CRITERIA MET	YES	NO
Tumor area circled on H&E slide		
Tumor cellularity meets specification		
Tumor surface area meets specification		
Gross tumor size provided to lab		
Number of positive nodes provided to lab		