Proteocyte AI

TEST REQUEST FORM

TO AVOID DELAYS PLEASE COMPLETE ENTIRE FORM

STRATICYTE™
Predict Oral Cancer Risk

FAX the following as a single submission, to **1 – 855 – 566 – 0488**
To prevent delays, please ensure all items are complete / included

This page is for instructional purposes only. Do not send this page with your request

- ☐ **Patient Information** including DOB, phone, email
- ☐ **Physician & Clinic Information** including NPI, State Lisc, etc
- ☐ **Payor -** Primary, Secondary Billing eg. Paid at Clinic; or Insurance, Medicare, etc
- ☐ **Biopsy** Information and **Specimen** #
- ☐ **ICD.10** code: K13.21 ; 29 ; 79, etc also lesion color(s)
- ☐ ***Patient/Caregiver Signature & Date***
- ☐ ***Physician Signature & Date***
- ☐ Patient **Facesheet**
- ☐ **Insurance** Cards (where applicable) clear, legible front + back copy
- ☐ **Pathology Report** in full
- ☐ **Clinic Notes** including *OPMD Dx*. *If referred, include referring Dr's notes*
- ☐ **Patient & Family HX-DX:** cancer?; lifestyle Fx; concurrent Dx; previous Bx, etc
- ☐ Images **of lesion**: if none exist, indicate in 'Notes & Concerns' section
- ☐ **ABN**: Advance Beneficiary Notice for STRATICYTE (Medicare); **Patient must sign-back**
- ☐ **LMN**: STRATICYTE is medically-necessary (*guide* avail on request)

Please ensure the Patient and-or Caregiver is made aware / understands that :

- Information provided by STRATICYTE acts as an adjunct to the existing H&E / Pathology Report.
- STRATICYTE's 5-Year Risk Score indicates the patient's individual probability of their OPMD becoming an OSCC (ref Patient Brochure)
- Although initiated simultaneously, Insurance and/or Medicare/Medicaid claims may be processed by the Insurer after the test is complete. If Proteocyte receives an ADR (additional documentation request) from the Insurer, Proteocyte will relay documents as provided by the Clinic/HCP (ref checklist above)
- If the Insurer denies the claim in part or in whole, the Patient and/or Clinic will be contacted regarding any remaining balance. (ref ABN, above; attached as p4 of TRF)

Thank you for choosing STRATICYTE, and your commitment to improving OPMD patient care & outcomes.

Email: clientservices@proteocyte.com **Phone:** 1-833-5-PROTEO (1-833-577-6836) **Fax:** 1-855-566-0488

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PATIENT INFORMATION

Complete the following or attach CLEAR, LEGIBLE copy of Patient Facesheet

Last Name	First Name	MRN
Date of Birth (DD-MMM-YYYY)	Sex at Birth ☐ Female ☐ Male ☐ Decline to Answer	Last 4 digits of SSN
Address	City	
	State	Zip Code
Phone	Email	
Caregiver Name	Relation to Patient	
Caregiver Phone	Caregiver Email	

PRIMARY BILLING

Complete the following or attach CLEAR, LEGIBLE copy of front & back of Insurance Cards

1RY PAYOR: ☐ Patient ☐ Commercial ☐ Medicare FFS ☐ Medicare ADV ☐ Medicaid FFS ☐ Managed Medicaid

Policy Holder Name	Date of Birth (DD-MMM-YYYY)
Plan Name	Plan Type ☐ HMO ☐ HDHP ☐ PPO ☐ POS ☐ Other _____
Member ID	Group ID
Plan Phone	Plan Fax
Dental Insurance Plan	Dental Phone

SECONDARY BILLING

Complete the following or attach CLEAR, LEGIBLE copy of front & back of Insurance Cards

2DY PAYOR: ☐ Patient ☐ Commercial ☐ Medicare FFS ☐ Medicare ADV ☐ Medicaid FFS ☐ Managed Medicaid

Policy Holder Name	Date of Birth (DD-MMM-YYYY)
Plan Name	Plan Type ☐ HMO ☐ HDHP ☐ PPO ☐ POS ☐ Other _____
Member ID	Group ID
Plan Phone	Plan Fax
Coordination of Benefits (if known)	

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BIOPSY INFORMATION

In addition to the below, attach full Pathology Report

SPECIMEN / ACCESSION #

☐ Pathology Report(s) attached

☐ Biopsy images attached — No pics?, ref in Notes & Concerns

BIOPSY DATE (DD-MMM-YYYY)

TYPE
☐ INCISION ☐ EXCISION

SITE to specify location (left/right; upper/lower; anterior/posterior; ventral/dorsal; medial/lateral; etc) *use 'Other' field*
☐ LIP ☐ TONGUE ☐ BUCCAL ☐ Tooth Area? _____
☐ PALATE ☐ FLOOR ☐ GINGIVA ☐ *Other* _____

ICD.10.CM

☐ **K13.21** Leukoplakia, incl tongue ☐ **K13.70** Lesions/oral mucosa, unspec. **COLOR(s)** ☐ Red ☐ White ☐ Mixed
☐ **K13.29** Oral dist, incl tongue ☐ **K13.79** Other lesions, oral mucosa ☐ *Other* _____

DYSPLASIA

☐ LOW-GRADE ☐ HIGH-GRADE

☐ MILD ☐ MODERATE ☐ SEVERE

☐ NONE ☐ *Other* _____

NOTES / CONCERNS (Patient Hx; Family Hx; Lifestyle factors; Concurrent illness; Previous biopsy, etc)

STRATICYTE INFORMATION — TEST REQUESTED

Uses a proprietary algorithm from a cohort of known outcomes to assess the **patient's individual STRATICYTE Risk Score**: **the 5-year probability of their OPMD** (oral potentially malignant disorder) **progressing to an OSCC** (oral squamous cell carcinoma). STRATICYTE acts as an adjunct to the corresponding Pathology report. *This test is not appropriate for lesions diagnosed as carcinoma.*

PHYSICIAN & CLINIC INFORMATION

Complete the below in full

ORDERING PHYSICIAN

SPECIALTY ☐ DDS ☐ DMD ☐ ENT ☐ MD ☐ OMS ☐ ORT ☐ ONC ☐ PD ☐ PER ☐ PRO

ADDRESS

ORDERING PHYSICIAN EMAIL (direct HCP *work* email preferred)

CITY

ORDERING PHYSICIAN PHONE (direct HCP *work* phone; NO general line)

STATE

ZIP

Clinic Manager / Director NAME

TYPE ☐ ASC ☐ DENTIST ☐ HOPD ☐ LAB ☐ MDO ☐ Other _____

Clinic Manager / Director EMAIL (direct email; NO general inbox)

Main Phone

Main Fax

Clinic Manager / Director PHONE (direct line; NO general reception)

STATE LISC #

Clinic Manager / Director FAX (if separate from Clinic; direct # only)

MEDICAID ID #

ORDERING PHYSICIAN NPI

CLINIC NPI

MEDICARE PTAN

Email: clientservices@proteocyte.com **Phone:** 1-833-5-PROTEO (1-833-577-6836) **Fax:** 1-855-566-0488

PATIENT CONSENT / AUTHORIZED SIGNATURE & DATE — REQUIRED

I understand that my biopsy as provided to the Pathologist will be collected, transported, and delivered to Proteocyte AI to assess the 5-Year risk that my OPMD (oral potentially malignant disorder) will transform to an OSCC (oral squamous cell carcinoma). I have been informed by my treating Clinician that the STRATICYTE test will act as an adjunct to its corresponding Pathology Report. I have further been informed by my 'clinician as to the purpose, scope, and limitations of such test. I understand the results of the test will be sent / made available to my treating Clinician, and that I will collect such information from my treating Clinician at that time. I have been informed and am aware of who may have access to my biopsy sample and/or test results, which include confidential PHI (protected health information). I understand that my PHI will be securely handled by Proteocyte AI for administration of services, data processing, billing, and reimbursement. I hereby give consent to such processing and storage of my PHI, and am aware I may revoke this consent at any time. I have read this form, and agree to undergo the test. I confirm I have had the opportunity to ask any questions I may have regarding this test and its process, and have received satisfactory answers from my treating Clinician.

Patient Signature	Print Name	Date (DD-MMM-YYYY)

PHYSICIAN SIGNATURE & DATE — REQUIRED

I hereby authorize testing and confirm that informed consent has been obtained from the patient, for relevant information to be released to Proteocyte AI for fulfillment of the test. I attest that, as the Ordering Physician, I am authorized by law in the relevant jurisdiction to order the test requested herein. By signing this form, I further attest the patient meets inclusion criteria as stated in the 'Test Requested' section above, the information as provided in this form is correct and belongs to the patient named above. I have had a discussion prior to ordering this test, on the potential results, and have determined to use these results to guide patient management.

Ordering Clinician Signature	Print Name	Date (DD-MMM-YYYY)

Notifier | Patient Name | Medicare Member Number

MEDICARE ABN (Advance Beneficiary Notice)

NOTE: If Medicare doesn't pay for the STRATICYTE test below, you may have to pay.
Medicare does not pay for everything, even some care you or your healthcare provider have good reason to think you need. Medicare may not pay for the STRATICYTE test.

Item / Service requested	Reason Medicare May Not Pay:	Estimated Cost
STRATICYTE test Straticyte uses a proprietary algorithm based on a cohort of known outcomes to **determine my personal Straticyte Risk Score**: **the 5-year probability of my diagnosed OPMD (**oral potentially malignant disorder) **progressing to an OSCC** (oral squamous cell carcinoma). Straticyte acts as an adjunct to the corresponding Pathology report to help guide my HCP in making informed choices to shape my treatment plan.	**Lack of Medical Necessity** -- item/service deemed not medically necessary. **Experimental / Investigational** -- item/service deemed experimental or investigational. **Frequency** -- item/service limited to (#) claims. **Non-Contract in Competitive Bidding** -- item/ service provided by a non-contract supplier in a competitive bidding area. **Not Covered** -- not all items/services are covered.	USD $

WHAT YOU NEED TO DO NOW:

- Read this form in full, so you can make an informed decision about your care.
- Ask us any questions you may have after you finish reading.
- Choose an option below about whether to receive the STRATICYTE test.

NOTE: For Option 1 or 2, we may help you use other insurance you may have, but Medicare cannot require us to do this.

OPTIONS: Check only one box. We cannot choose a box for you.

◉ **OPTION 1** **I want the STRATICYTE test**. I understand I may be asked to pay now, but I also want Medicare billed for an official decision on payment, sent to me in a MSN (Medicare Summary Notice). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, I will be refunded any payment made, less co-payments or deductibles.

○ **OPTION 2** **I want the STRATICYTE test**, but do not want to bill Medicare. I understand I may be asked to pay now, as I am responsible for payment. I cannot appeal if Medicare is not billed.

○ **OPTION 3** **I do not want** the STRATICYTE test. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

Additional Information: **This notice gives our opinion. It is not an official Medicare decision.**
Signing below means you have received and understood this notice. You may ask to receive a copy. If you still have questions, call **1-800-MEDICARE** (1-800-633-4227) **TTY**: (1-877-486-2048)

Patient Signature:	**Date:**

Print Name Medicare # DD-MMM-YYYY

You have the right to get Medicare information in an accessible format like large print, Braille, or audio.
You also have the right to file a complaint if you feel you've been discriminated against.
Visit Medicare.gov/about-us/accessibility-nondiscrimination-notice.