Proteocyte AI

TEST REQUEST FORM

TO AVOID DELAYS PLEASE COMPLETE ENTIRE FORM

STRATICYTE™
Predict Oral Cancer Risk

To prevent delays, please ensure all items are complete / included
[E] CLIENTSERVICES@PROTEOCYTE.COM [F] 1 – 855 – 566 – 0488

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(s)** 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. **Patient must sign and date**
- ☐ **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; website)
- Although initiated simultaneously, Insurance/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, and may request further files as required by the Insurer. (ref checklist above)
- If Insurance/Medicare/Medicaid denies the claim in part or in whole, the Patient and/or Clinic may be contacted regarding any remaining balance. (ref ABN; 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 #

☐ 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
☐ **K13.29** Erythroplakia / oral dist's
☐ **K13.70** Lesions/oral mucosa, unspec.
☐ **K13.79** Other lesions, oral mucosa
☐ *Other* _____

COLOR(s) ☐ Red ☐ White ☐ Mixed

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

ADDRESS

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

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**

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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)

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TEST REQUEST FORM
ABN: Advance Beneficiary Notice
Insurance/Medicare/Medicaid

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If your (Insurance/Medicare/Medicaid) **provider doesn't pay for the STRATICYTE test, you may be required to pay.** Your (Insurance/Medicare/Medicaid) provider does not pay for everything, even some care you or your healthcare provider have good reason to think you need. This notice does not give an official decision. Signing below means you have received and understood this notice.
For questions about coverage, contact your (Insurance/Medicare/Medicaid) provider.

WHAT YOU NEED TO DO: Patient Mbr #

- **Read this in full and ask any questions** you may have, so you can make an informed decision.
- **Choose the option you prefer** regarding the STRATICYTE test.

Item / Service requested	Reason (provider) may not pay	est. Cost
STRATICYTE Straticyte is a MAAA -classed ADLT utilizing a proprietary algorithm from a cohort of known outcomes t**o determine my personal Straticyte Risk** score: **the 5-year probability of my diagnosed OPMD** / oral lesion (potentially malignant disorder) **progressing to an OSCC** / oral cancer (squamous cell carcinoma). Straticyte acts as an adjunct to the Pathology report, **helping my HCP make informed choices to shape my treatment plan & manage my clinical care**	**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, competitive bidding area. **Not Covered** -- not all items/services are covered.	$500 USD

I, have read & understood this form. I choose:

☐ **OPTION 1** **I want the STRATICYTE test**, and I also want my (Insurance/Medicare/Medicaid) provider billed. I understand I may be asked to pay now, and that if my provider doesn't pay, I am responsible for payment. I also understand I can appeal to my provider by following the directions they supply. If my (Insurance/Medicare/ Medicaid) provider does pay, I will be refunded any payment made less co-payments or deductibles.

☐ **OPTION 2** **I want the STRATICYTE test**, but I do not want my (Insurance/Medicare/Medicaid) provider billed. I understand I may be asked to pay now, as I am responsible for payment. I cannot appeal if my provider (Insurance/Medicare/Medicaid) is not billed.

☐ **OPTION 3** **I do not want the STRATICYTE test**, and acknowledge my (Insurance/Medicare/Medicaid) provider will not be billed (Insurance/Medicare/Medicaid). I understand with this choice I am not responsible for payment, and I cannot appeal to see if my (Insurance/Medicare/Medicaid) provider would pay.

Patient Signature: **Date:**

Print Name Member # DD-MMM-YYYY

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