Optigyte®
Amniotic Ocular Matrix

Physician Office Payment & Billing Guide **2020**

Reimbursement Support Line
Phone: (919) 921-8105 Ext 119
Fax: (919) 267-3753

MERAKRIS THERAPEUTICS

Introduction

Thank you for choosing to treat your patient with Opticyte Amniotic Ocular Matrix. This booklet contains information on commonly used procedure and diagnosis codes that you may choose to utilize when billing for the use of the product.

Opticyte Amniotic Ocular Repair Matrix (Opticyte Matrix®) is a human amniotic membrane disc processed to retain the native extracellular matrix properties and morphologic structure. Opticyte Matrix provides an ophthalmic barrier to the corneal surface and supports cell attachment and ingrowth post-surgical treatment. Opticyte Matrix® is intended for use as a protective covering and extracellular matrix corneal support. When used as a corneal surface barrier, Opticyte Matrix® is intended to provide an optimal biological barrier during the healing/re-epithelialization of the cornea with minimal scarring.

Opticyte Amniotic Ocular Matrix is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues, and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1270 and 1271.

For treatment with Opticyte, providers will bill insurers for the procedure of applying the product. This guide explains commonly accepted practices and codes to complete these claims.

Insurance Coverage for Opticyte

Medicare and commercial insurance companies may cover an item or service considered reasonable and necessary for the treatment or diagnosis of a beneficiary. Insurers frequently provide tacit coverage for a product or procedure and may not issue a formal coverage statement. In fact, neither Medicare nor private insurance companies have published coverage policies for many items and services. Thus, as with many services, the use of Opticyte in ocular procedures should be covered with sufficient documentation of the of the product.

Physician offices complete the CMS-1500 claim form, often filled out and submitted electronically, and includes documentation for use of Opticyte. Hospitals, including the outpatient department, complete the UB-04 form. Providers fill in codes for the diagnosis, the product (in this case Opticyte), and the procedure. The code representing Opticyte is currently a general code that does not specifically identify the product, so additional documentation including the product invoice, may be required. However, since Medicare subsumes this code into the procedure code as a supply integral to the procedure, providers should expect payment for the overall procedure (including utilization of Opticyte).

Merakris Reimbursement Support Line

For assistance with reimbursement questions, contact the Merakris Reimbursement Support Line at (919) 921-8105 x 119.

Normal business hours are 8:00 am - 7:00 pm eastern time.

Merakris Reimbursement Support Line staff can assist with the following:

- Patient-specific insurance verifications
- Payer policy and Medicare Local Coverage Determination (LCD) information
- Nurse Case Manager review of documentation and coding
- Prior authorization and pre-determination support
- Individual claims support
- General coding and reimbursement questions
- Denials Management/ Appeals

Provider Responsibility: The provider is responsible for verifying individual contract or reimbursement rates with each payer. The Support Line is not able to confirm contracted or reimbursable rates on your behalf.

How to Request Reimbursement Support?

Before Merakris will provide any reimbursement services, the healthcare facility must submit a complete **Insurance Verification Request Form** (Page 12) with a signed practitioner authorization or signed patient authorization and fax to (919) 267-3753.

Coding & Payment

Product Code – The HCPCS code **V2790** represents an amniotic membrane for surgical reconstruction, per procedure. Please note, V2790 does not specifically identify Opticyte. Thus, providers may need to provide additional information to identify the product so that the claims processor understands what V2790 signifies. Medicare will not pay for V2790 separately, but it is still essential to include the code on claims to Medicare. Commercial plans may pay separately for Opticyte, so it is also essential to include it on their claims as well. Essential information includes stating the name and quantity of the product in Box 19 on the CMS-1500 and Box 80 on the UB-04 claim forms. Sample claim forms are included in this booklet.

For physician services, Column 24B of the CMS-1500 claim form notes the Place of Service code for the procedure performed. The physician office setting is Place of Service (POS) 11, the hospital outpatient department is POS 22 and the ambulatory surgical center is POS 24. This POS code should be on the claim so that the insurer knows how to process the form.

Procedure Code – These codes identify common procedures used when applying Opticyte.

Procedure Codes and 2020 Medicare National Average Payments for Physician Services

CPT Code	Description	2020 Medicare Physician Fee Schedule Payment Amount (Non-Facility, or Office)	2020 Medicare Physician Fee Schedule Payment Amount (Facility like HOPD or ASC)
65426	Excision or transposition of pterygium; with graft	$679.57	$488.79
65778	Placement of amniotic membrane on the ocular surface; without sutures	$1,436.37	$55.94
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured	$1,242.56	$154.10
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers	$679.93	$679.93
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft	$1,163.17	$1,163.17
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir	$864.71	$864.71

Procedure Codes and 2020 National Average Payments for Hospitals and ASCs

CPT Code	Description	2020 APC Code in Hospital Outpatient Department	2020 Medicare Hospital Outpatient Payment Amount	2020 Medicare ASC Payment
65426	Excision or transposition of pterygium; with graft	5503 – Level 3 Extraocular Repair	$1,935.20	$836.94
65778	Placement of amniotic membrane on the ocular surface; without sutures	5502 – Level 2 Extraocular Repair	$806.97	N/A
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured	5114 – Level 4 Extraocular Repair	$5,981.95	N/A
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers	5114 – Level 4 Extraocular Repair	$5,981.95	$1,355.63
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft	5492 – Level 2 Intraocular Procedure	$3,818.33	$2,462.24
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir	5491 – Level 1 Intraocular Procedure	$2,021.86	$1,012.72

Modifiers – Please check with the Medicare contractor or commercial insurance company to determine whether modifiers to the CPT code are required. The following modifiers are common examples:

50 – Bilateral procedure
LT – Left eye
RT – Right eye
59 – Distinct procedural service

Diagnosis Codes – Healthcare providers use ICD-10-CM diagnosis codes to describe their patients' conditions that warrant the treatment described in the claim. The ICD-10-CM code is placed on the claim form (or in electronic format) in Box 21 of the CMS-1500 and in Box 66 of the UB-04. Following are typical ICD-10-CM codes you may choose to use for patients who receive Opticyte. Providers may need to code for the specific regions, body parts and lateral areas that specify the diagnosis beyond the code headers. Following are examples of diagnosis codes and diagnosis code headings (the first four digits of the code) that providers may specify when treating a patient with Opticyte. The contents of the table are for example only as there may be additional or different diagnoses requiring such treatment.

For all of the codes below, providers may specify which eye(s) in the sixth digit, as follows:

HXX.XX1 – right eye
HXX.XX2 – left eye
HXX.XX3 – bilateral
HXX.XX9 - unspecified

ICD-10-CM Code	Description
H11.0	Pterygium of eye
H11.1	Conjunctival degenerations and deposits
H11.22	Conjunctival granuloma
H11.23	Symblepharon
H11.42	Conjunctival edema
H11.82	Conjunctivochalasis
H16.0	Corneal ulcer
H16.1	Other and unspecified superficial keratitis without conjunctivitis
H16.2	Keratoconjunctivitis
H17.1	Central corneal opacity
H17.8	Other corneal scars and opacities
H18.1	Bullous keratopathy
H18.42	Band keratopathy
H40.10	Open angle glaucoma
H40.11	Primary open angle glaucoma
H40.20	Primary angle-closure glaucoma
H40.22	Chronic angle-closure glaucoma
H40.23	Intermittent angle-closure glaucoma
H40.3	Glaucoma secondary to eye trauma
H40.4	Glaucoma secondary to eye inflammation
H40.5	Glaucoma secondary to other eye disorders
H40.6	Glaucoma secondary to drugs
H40.8	Other glaucoma
H42	Glaucoma in diseases classified elsewhere (Code underlying condition first)
H59.01	Keratopathy (bullous aphakic) following cataract surgery

Tips to obtain coverage and payment

Include all documentation with the claim, including invoice and description of V2790 in Box 19 of the CMS 1500 claim form and Box 80 of the UB-04 claim form. For Medicare claims, providers can expect payment for the overall procedure using the appropriate procedure code without separate payment for V2790.

The description may be the following:

"Opticyte Amniotic Ocular Matrix, x unit(s)"

Claim rejection is not a denial based on medical necessity. The rejection is an administrative action because the claim will not move through the process because of incomplete information.
To help move the claim through the payment process, providers should include documentation for the use of Opticyte. Documentation includes a description of the product, medical justification through a letter of medical necessity, and the invoice. Samples of the claim form and a template letter of medical necessity are included in this booklet.

Once the claim is moving through the process and you have submitted additional documentation, the turnaround time for the payment may not be as rapid as it is for claims considered complete or clean. Insurers may not make payments on these types of claims until 45 to 60 days after submission, a normal time frame for flagged claims. Additionally, each carrier has timely filing guidelines for refiles/appeals and practices need to be aware of these for all the plans they participate with, as well those that they are not in network with.

For details and ordering information on Opticyte, please contact your sales representative, or our customer service department at 919-921-8105.

Disclaimer

The information in this document is gathered from public sources and is provided here for illustrative purposes only. This information cannot cover all situations or all third-party payer rules or policies, nor can use of this information guarantee coverage or payment. This document makes no other representations or warranties as to selecting codes for procedures or compliance with any other billing protocols or prerequisites. As with all claims, individual providers and suppliers are responsible for exercising independent clinical judgment in selecting the codes that most accurately reflect a patient's condition and the procedures performed. Laws, regulations, and policies concerning coding and payment are complex and subject to change. You should refer to current, complete and authoritative publications such as Medicare transmittals, AMA CPT lists, and third-party insurer policies as the basis for selecting codes that describe care rendered to an individual patient, and you may wish to contact individual payers as needed.

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

PICA

1. MEDICARE ☐ (Medicare#) MEDICAID ☐ (Medicaid#) TRICARE ☐ (ID#/DoD#) CHAMPVA ☐ (Member ID#) GROUP HEALTH PLAN ☐ (ID#) FECA BLK LUNG ☐ (ID#) OTHER ☐ (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M ☐ F ☐

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self ☐ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)

CITY | STATE

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE | TELEPHONE (Include Area Code) ( )

ZIP CODE | TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES ☐ NO ☐

a. INSURED'S DATE OF BIRTH MM DD YY SEX M ☐ F ☐

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES ☐ NO ☐ PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES ☐ NO ☐

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES ☐ NO ☐ *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government b… ment below.

SIGNED

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY MM DD YY QUAL.

QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES ☐ NO ☐ $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service

A. B. C.

E. F. G.

I. J. K.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1									NPI	
2									NPI	
3									NPI	
4									NPI	
5									NPI	
6									NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES ☐ NO ☐

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARR

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Item 19 – Enter Product Name, NDC, WAC, WAC per sq cm, source of WAC

Item 24D/1 – Enter Product HCPCS Code and modifier(s)

Item 24 F - Enter Charges

Item 21 - Enter Diagnosis code(s)

Item 21 B – Enter Place of Service

Item 24D/2 – Enter CPT Code for Application

Item 24 G – Enter Units (cm2)

Template Letter of Medical Necessity

Please note that you will need to provide information to ensure that this template is completed in a manner that describes your services provided for the specific patient's condition, including a description of how you used Opticyte.

[Physician Office Letterhead]

Date

Medical Director
Insurance Company/Medicare Administrative Contractor (MAC)
Address
City, State ZIP

RE: Patient Name
Policy ID Number

Dear Dr. _____:

On behalf of my patient, [PATIENT NAME], this letter serves as a request for individual coverage and provides clinical information on this patient's condition. I am confident you will find that the services provided and the use of Opticyte Amniotic Ocular Repair Matrix. This letter and its supporting documents will provide you with a better depiction of this patient's clinical history and this patient's need for Opticyte.

[INSERT PATIENT'S NAME] presented to me with [Describe specific symptoms, your diagnosis (using ICD-10-CM code) and the planned treatment].

Description of Procedure: [Please describe the procedure performed and the necessity of Opticyte]

Ocular Amniotic Membrane Description: Opticyte Amniotic Ocular Repair Matrix is human amniotic membrane disc processed to retain the native extracellular matrix properties and morphologic structure. Opticyte provides an ophthalmic barrier to the corneal surface and supports cell attachment and ingrowth post-surgical treatment. Opticyte is intended for use as a protective covering and extracellular matrix corneal support for uses that includes, but is not limited to, procedure [1, 2, 3 and 4]. When used as a corneal surface barrier, Opticyte is intended to provide an optimal biological barrier during the healing/re-epithelialization of the cornea with minimal scarring.

Opticyte Amniotic Ocular Matrix is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues, and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1270 and 1271.

Patient's Clinical Need for Opticyte: [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments have included [DESCRIBE CONSERVATIVE CARE, USE OF MEDICATIONS, PRIOR TREATMENTS, and PHYSICAL AIDS].

In a discussion with [INSERT MR./MS.] following an exam, a decision was made to move forward with a skin substitute graft procedure

I have attached the patient's chart notes and FDA registration letter for Opticyte. Should you have further questions or concerns, please call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and anticipated authorization of these services for your insured.

Sincerely,

[PHYSICIAN NAME], [DEGREE]

MK-0007.00

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3013695841

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2020
Last Registration Receipt Date: 12/11/2019
Summary Report Print Date: 01/07/2020

Legal Name and Location:

Merakris Therapeutics, LLC
800 Park Offices Drive
Suite 3322

Research Triangle Park, North Carolina 27709
USA

Phone: 919-921-8105 **Ext.:** 110

Reporting Official:

Christopher Broderick, President
PO Box 12712
Research Triangle Park, North Carolina 27709
USA
Phone: 919-921-8105 Ext. 110
cbroderick@merakris.com

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI No.:
Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane							X	X	X			***See full text on next page.
Blood Vessel												
Bone							X	X	X			
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Amniotic Fluid (Dermacyte® Amniotic Wound Care Liquid): store, distribute, and label.

Proprietary Name(s):		
	Amniotic Membrane	Dermacyte® Wound Matrix, Opticyte¿ Ocular Matrix

FEI: 3013695841

Legal Name: Merakris Therapeutics, LLC

Optigyte Amniotic Ocular Matrix

Insurance Verification Request

Please fax completed form to:
(919) 267-3753

Practice Information

Practice Name:

Primary Contact Name:

Primary Contact Phone:	Primary Contact Fax:
Group NPI:	Rendering Provider:
Tax ID:	Individual Provider NPI:
Practice Location:	Service Location: (Write same if same)

Patient Demographic Information

Patient Name:	Patient DOB:

Policy Holder Relationship: Self, Spouse, Child, Other:

Policy Holder Name:

Insurance Information

Primary Insurance Carrier:

Plan Name:

Policy #:	Group #:

Provider Services Phone Number (Found on back of card):

Secondary Insurance Carrier:

Plan Name:

Policy #:	Group #:

Provider Services Phone Number (Found on back of card):

Visit Information

Planned Date of Service:

Patients ICD 10 Diagnosis Codes:

1) 2) 3) 4)

Planned Procedure CPT Codes:

Opticyte®
Amniotic Ocular Matrix

Contact Us

For information related to Opticyte Insurance benefit verifications, prior authorization assistance or claims appeal assistance, please contact our Reimbursement Support Line.

Phone: (919) 921-8105 Ext 119
Fax: (919) 267-3753
Email: support@merakris.com
https://merakris.com/ocular-therapeutics/

MERAKRIS THERAPEUTICS