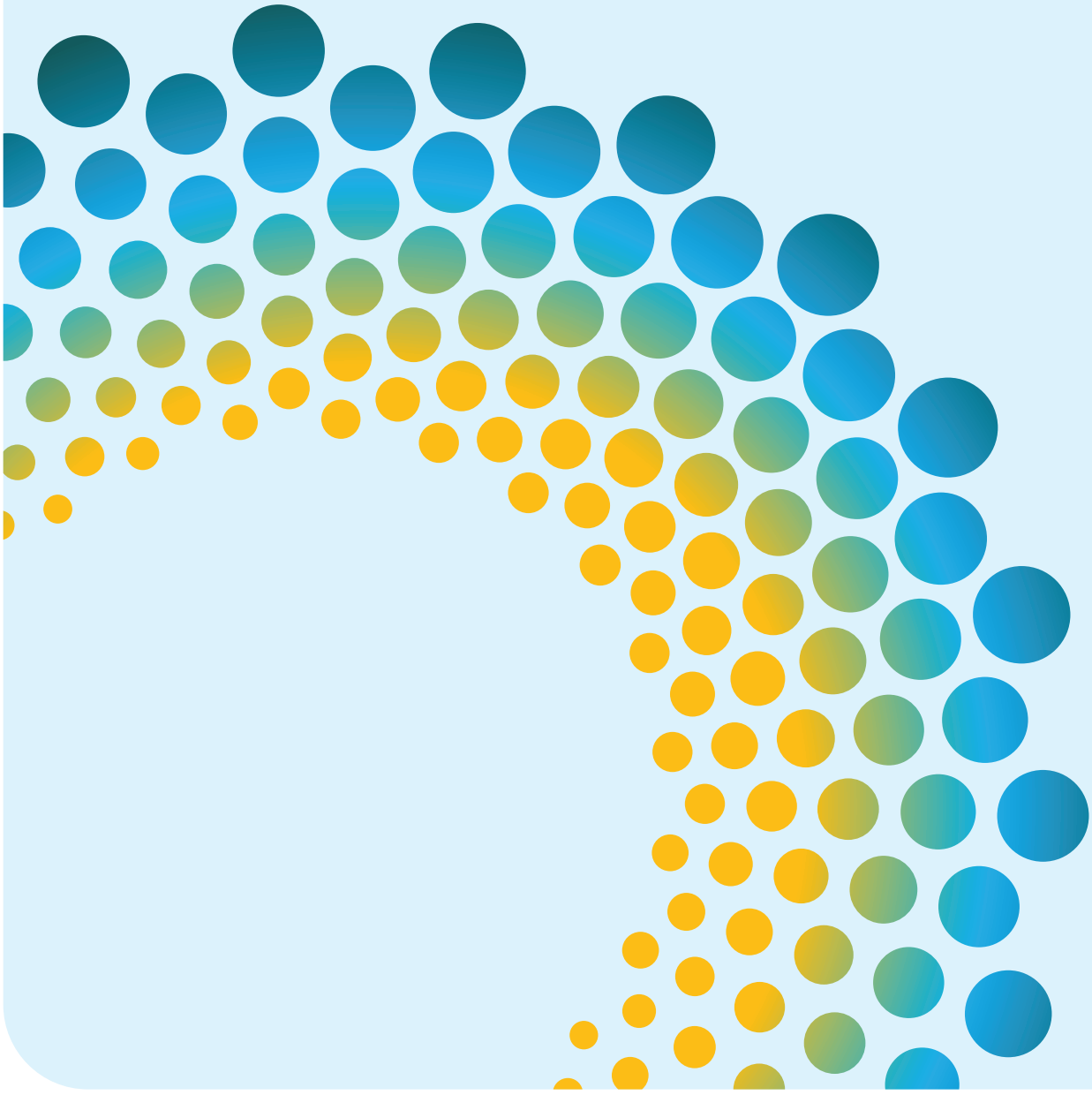
Brightstar™ Therapeutics Reimbursement Guide

BrightMEM™ Corneal Allograft

2025



Transforming the Treatment of Corneal & Ocular Surface Disease

BRIGHTSTAR™ THERAPEUTICS

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Introduction

Brightstar Therapeutics is dedicated to providing its customers with professional reimbursement and medical claims assistance at no charge. Our aim is to support billing for BrightMEM corneal allograft to Medicare and other commercial insurance carriers. In collaboration with NMD Healthcare, we offer guidance on coding, coverage, and reimbursement inquiries.

This comprehensive guide is designed to assist surgeons and facilities performing corneal transplants in effectively billing for reimbursement through Medicare and commercial payers.

Product Description

BrightMEM Anterior Keratoplasty (BMAK) is a surgical procedure that utilizes BrightMEM, an innovative corneal allograft composed of Descemet's Membrane that promotes corneal re-epithelialization and functions as a robust basement membrane with natural long-term durability.

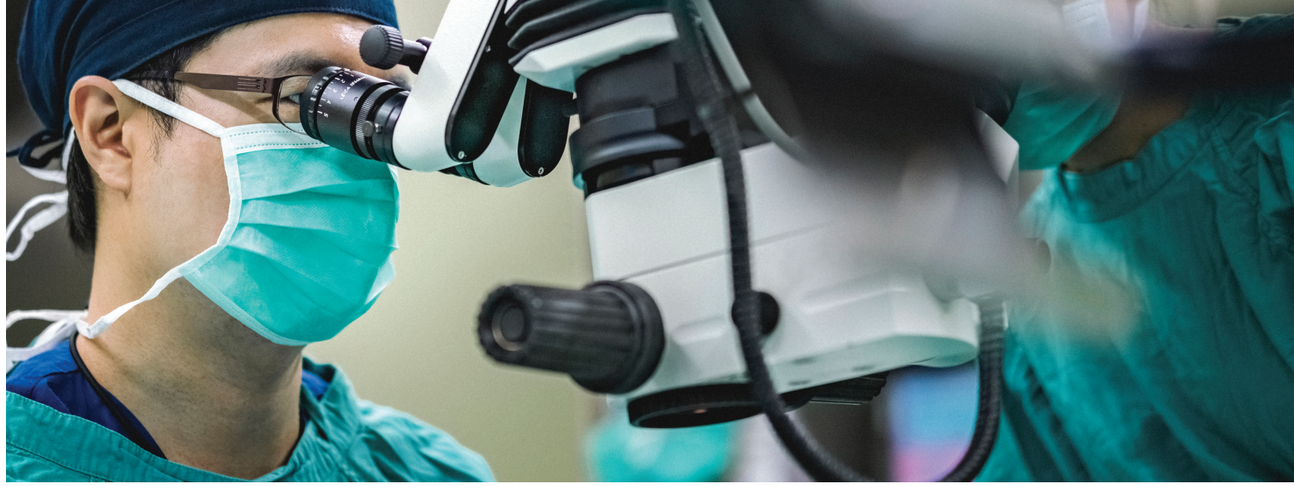
The product is aseptically processed from tissues obtained from donated human tissue (corneas) according to the current Good Tissue Practices (cGTP) regulations established by the US Food & Drug Administration (FDA).

Reimbursement for the Acquisition of Corneal Tissue

Medicare provides separate payment to hospital outpatient departments and Ambulatory Surgery Centers for corneal tissue acquisition used in corneal surgeries.

This payment is in addition to the payment to the surgeon. The reimbursement for corneal or donor tissue acquisition is based on the cost and is not included in the outpatient prospective payment system or the APC payment for the surgical procedure. To receive this cost-based reimbursement, the hospital outpatient department must bill separately for the corneal or donor tissue acquisition using HCPCS code V2785 on the UB-04 hospital claim form. Under the ASC payment system, Medicare makes separate payments to ASCs for corneal tissue acquisition. Payment is based on acquisition cost or invoice." Report V2785 on the Medicare 1500 claim form submitted to payers.

The Eye Bank Association of America and AAO have provided further information about the appropriate billing of the cost for the acquisition of corneal tissue at:
restoresight.org/medicare-reimbursement.



Coding Overview

DEFINITION OF PROCEDURE:

- Procedure code CPT® 65710 is a billing code when performing anterior lamellar keratoplasty [LK].

CPT® CODE 65710:

- CPT® 65710 has a code descriptor of "Keratoplasty (corneal transplant); anterior lamellar."

APPLICABLE ICD-10-CM CODES:

- Providers are required to bill ICD-10 diagnosis codes to describe the patient's medical condition and to justify medical necessity for the supplies and services furnished to the patient. Providers should always report ICD-10 diagnosis codes that most accurately reflect the patient's condition to the greatest degree of specificity possible.
- Limbal stem cell deficiency (disorder) causing conjunctivalisation will be coded with ICD-10-CM Diagnosis code H18.8. Some commonly reported ICD-10 diagnosis codes are H18.891,H18.892, H18.893, H18.899. Note that this may not be an all-inclusive list of viable ICD-10 diagnosis codes.
- For additional listing of possible ICD-10-CM diagnosis codes that may map to limbal stem cell deficiency contact your local Medicare Administrative Contractor [MAC] for questions regarding the billing of any ICD-10 diagnosis code(s) that may map to CPT® 65710 that is not listed on the professional society's list of commonly billed ICD-10 diagnosis codes.

NATIONAL CORRECT CODING INITIATIVE (NCCI):

- NCCI edits are released by CMS to prevent improper payments when incorrect combination of CPT codes are billed by the same provider for the same patient on the same date of service.
- For example, do not report CPT® code 65435 with CPT® code 65710 as under the National Correct Coding Initiative [NCCI] guidelines, CPT® 65435 is a Column II code to CPT® 65710 a Column I code and therefore CPT® 65435 will be edited out on the claim and not paid.

Facility [ASC] Payments:

Ambulatory Surgical Center (ASC)
CY 2023 Medicare National Payment Rates / January 1, 2025

CPT Code	Short Descriptor	Subject to Multi-Proc Discount	PI[T]	Payment Rate 2024	Payment Rate 2025	2024 to 2025
65710	Keratoplasty (corneal transplant); anterior lamellar	Y	A2	$2,585.54	$2,628.34	1.66%
V2785	Processing, preserving and transporting corneal tissue	N/A	F4	F4	F4	N/A

[T]See Notes for definitions of payment indicators on page 7

Ref: CMS January 2025 Addendum B payment file
Medicare makes a separate payment for corneal tissue acquisition cost or invoice

ASC: License Agreement | CMS

Physician [MPFS] Payments:

Medicare Physician Fee Schedule (MPFS)
CY 2024 Medicare National Payment Rates / January 1, 2025

CPT Code	Long Descriptor	Status	Facility ASC/HOPPS Payment Rates 2024	2025	2024 to 2025
65710	Keratoplasty (corneal transplant); anterior lamellar	A	$1,108.25	$1,092.99	-1.38%
V2785	Processing, preserving and transporting corneal tissue	X	Statutory Exclusion	Statutory Exclusion	N/A

[T]See Notes for definitions of Status Codes on page 8

Ref. 2025 National Physician Fee Schedule Relative Value File, release dated December 22, 2024.
Conversion Factor (CF) is 32.35 announced by CMS on November 1, 2024

MPFS: CMS-1807-F | CMS

Hospital [HOPPS] Payments:

Hospital Outpatient Prospective Payment System (OPPS)
CY 2024 Medicare National Payment Rates January 1, 2025

CPT Code	Short Descriptor	SI[T]	APC	Payment Rate 2024	Payment Rate 2025	2024 to 2025
65710	Keratoplasty (corneal transplant); anterior lamellar	J1	5493	$4,979.80	$5,159.71	3.61%
V2785	Processing, preserving and transporting corneal tissue	F	N/A	F	F	N/A

[T]See Notes for definitions of Status Codes on page 8

Ref: CMS January 2025 Addendum B payment file

Medicare's payment for corneal tissue acquisition is paid on a cost basis, not under the Outpatient Prospective Payment System. To receive cost-based reimbursement, submit charges for corneal tissue acquisition using HCPCS code V2785.

HOPPS: License Agreement | CMS

Notes:

ASC PAYMENT INDICATORS:

A2 = Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.
F4 = Corneal tissue acquisition; hepatitis B vaccine; paid at reasonable cost.

ASC SUBJECT TO MULTI-PROCEDURE DISCOUNT:

Status Indicator "Y" = "When the ASC performs multiple surgical procedures in the same operative session that are subject to the multiple procedure discount, contractors pay 100 percent of the highest paying surgical procedure on the claim, plus 50 percent of the applicable payment rate(s) for the other ASC covered surgical procedures subject to the multiple procedure discount that are furnished in the same session.

The OPPS/ASC final rule for the relevant payment year specifies whether or not a surgical procedure is subject to multiple procedure discounting for that year. Final payment is subject to the usual copayment and deductible provisions."

MPFS STATUS CODES:

A = Active Code. These codes are paid separately under the physician fee schedule, if covered. These codes are separately payable under the PFS. There will be RVUs for codes with this status. The presence of an "A" indicator does not mean that Medicare has made a national coverage determination regarding the service. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy.

Notes (continued):

X = Statutory Exclusion. These codes represent an item or service that is not within the statutory definition of "physicians' services" for PFS payment purposes (for example, ambulance services). No payment may be made under the PFS and generally, no RVUs are shown for these codes.

HOPPS STATUS INDICATORS:

J1 = Hospital Part B Services Paid Through a Comprehensive APC. Paid under OPPS; all covered Part B services on the claim are packaged with the primary "J1" service for the claim, except the Comprehensive APC payment policy exclusions found in the most recent Addendum J.

F = Corneal Tissue Acquisition; Certain CRNA Services and Hepatitis B Vaccines. Not paid under OPPS. Paid at reasonable cost.

Commercial Payers

Prior to submitting a claim for BrightMEM corneal allograft to a commercial payer which may include Medicare Advantage plans, it is recommended that you review your negotiated provider contract to determine what has been agreed to between your facility / practice and the individual commercial payer.

All payer contracts are considered "confidential and proprietary" between the facility and the payer so any limitations regarding coverage, fee schedule allowables, claim reporting requirements and submission instructions contained in your specific agreement can only be accessed by the plan provider. Please note that all payer plans are different and subject to the terms of the individually negotiated contracts.

Each commercial payer benefit plan, summary plan description plan description, or contract will ultimately define what the plan member [patient] benefit services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions, or exclusions or if a Prior Authorization is required. If there is a discrepancy between a payer medical coverage policy and a member's plan description or contract that the benefit plan or contract will govern. While obtaining a Prior Authorization does not guarantee payment of a claim, it can prevent and reduce administrative claim denials due to lack of authorization on file when one is required.

FAQ

Frequently Asked Questions

WHAT HAPPENS IF I PERFORM ANOTHER TRANSPLANT PROCEDURE ALONG WITH A BRIGHTMEM™?

- When more than one surgical procedure is performed in the same operative session, the multiple surgery rule applies. Medicare will allow 100% of the highest payment surgical procedure on the claim plus 50% for the other ASC- covered surgical procedure furnished in the same session. If a 2nd tissue is issued it would be reduced by 50% as per the Medicare multiple surgical rule.

DO I HAVE TO PERFORM THIS PROCEDURE IN AN OPERATING ROOM?

- Under CMS guidelines, HCPCS V2785 for cornea donor tissue is eligible for separate reimbursement only in a hospital outpatient surgery setting or in an Ambulatory Surgery Center.

WHAT IF I NEED TO DO A REGRAFT WITHIN THE 90-DAY GLOBAL PERIOD?

- Based on Global Surgery guidelines, if the 2nd cornea tissue is unplanned than append with modifier -78 [Unplanned return to the operating / procedure room by the same physician or other qualified health care professional during the postoperative period].

IF TISSUE IS NOT COVERED BY INSURANCE, CAN THE PATIENT BE CHARGED?

- For Medicare, if prior to the surgery, the patient is informed by the surgeon or staff that their insurance plan does not cover the surgical procedure and donor tissue, then the use of the voluntary Advance Beneficiary Notice of Non-coverage (ABN) may help the patient decide whether to have the procedure performed since the patient insurance will not accept financial liability to pay. Note that when you issue a voluntary ABN, it has no effect on financial liability, and the patient isn't required to select an option or sign and date the notice.

CAN I BILL FOR THE TISSUE IF THE PROCEDURE WAS CANCELLED DUE TO UNFORESEEN CIRCUMSTANCES?

- CMS defines it as the following, "A procedure that was discontinued or ended before completion is not billed as a completed procedure and will not be paid for". You may submit the claim with Modifier -53 (Discontinued procedure) and accompanying medical records and full details of why the procedure was terminated before completion to receive any consideration of payment.

Contact Information:

For additional reimbursement information or questions regarding this coding and reimbursement guide, please contact Rusty Kelly, Chief Operating Officer at Brightstar Therapeutics via email at **rusty@brightstartx.com.** You may also submit your request for help via our reimbursement help form found at: **https://www.brightstartx.com/reimbursement-help-form.**

Disclaimer:

The educational information contained in this reimbursement guide is provided based on research as of January 2025, and is being provided with the understanding that Brightstar™ Therapeutics is not engaged in rendering legal or reimbursement advice.

Since Medicare (CMS) coding, coverage and reimbursement policies and regulations affecting those policies are subject to frequent change (and often vary from payer to payer), the reader is advised to routinely monitor United States federal coding guidelines and coverage policies to verify that the reimbursement information in this guide is up to date going forward. Policies and procedures published by payers and agencies such as the Centers for Medicare and Medicaid Services (CMS) take precedence over the information contained herein.

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THERAPEUTICS

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