EXECUTIVE SUMMARY

ISSUE
Corneal tissue used for graft procedures is frequently not billed to Medicare. Improper billing distorts the total costs of corneal graft procedures, and may affect reimbursement rates for Ambulatory Surgical Centers (ASCs) and hospitals.

Corneal tissue for transplant is reimbursed by Medicare as a “pass through” at reasonable cost. The data show that while Medicare paid for 74% of the nation’s corneal transplants only one third of the corneal tissue used in Medicare procedures was billed back to the Centers for Medicare and Medicaid Services (CMS), according to this analysis of Medicare claims submitted by providers in claims year 2010.

CONSEQUENCES
Failure to claim Medicare reimbursement for corneal tissue cost hospitals and ASCs more than $8 million for claims year 2010, with nearly 90% of the error occurring in hospitals. Because the cost of tissue is not being claimed for reimbursement, reimbursement rates may be distorted for today’s private payer system and for Medicare as policy moves forward with healthcare reform.

This could lead ASC managers to conclude that corneal transplant procedures are not cost effective—increasingly so in an era of healthcare reform in which costs are scrutinized—and lead to a decline in these treatments at suburban facilities. Corneal blind patients referred to hub hospitals may be unable to access hubs and so may go without treatment.

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SightLife has a mission to eliminate corneal blindness worldwide. In the United States, where the availability of donated corneas approaches matching 100% of the need, this means going beyond ensuring quality donated corneal tissue for transplant to advocate for better access to better healthcare.

While looking into issues of bottlenecks blocking patient access to treatments for corneal disease we uncovered systemic problems with public payer billing for corneal procedures and corneal tissue. Analysis identified incomplete bill claims for services provided to Medicare enrollees that may lead to under-reimbursement and other potentially serious consequences for the enduring Medicare coverage of corneal graft procedures in the era healthcare reform.

We undertook a research project based on Medicare claims from procedures done in 2010, the most recent year for which comprehensive data were finalized and made available. The purpose of this study was to identify any disparities in patient access to appropriate treatments for corneal blindness.

This study is primary research that blends data from hospital and ambulatory surgical center facilities, Medicare Administrative Contractor (MAC) records, and the Eye Bank Association of America (EBAA).

SightLife intends to continue to study the data the Centers for Medicare and Medicaid Services (CMS) make available annually. We will blend these data with private payer information to create better knowledge about how to improve the healthcare system for patients, physicians, and eye banks.

TRENDS IN DOMESTIC CORNEAL TRANSPLANTS

The Eye Bank Association of America (EBAA) reports that 42,170 corneal transplants were done in the United States in 2010. According to our analysis, the majority of these procedures (74%) were performed for patients participating in the traditional Medicare program.

Each year the EBAA reports on the leading indications for treatments involving donated eye tissue. Indicators with consistent prevalence include Fuchs' dystrophy, endothelial failure including post-cataract surgery edema, and keratoconus.4

Keratoconus affects the anterior of the cornea, so a full-thickness or anterior segment transplant is required for treatment. Fuchs' dystrophy and other endothelial dysfunctions are diseases of the posterior (endothelial) segment of the cornea, and may be treated with a removal of endothelial tissue and graft of donor endothelial tissue. A full-thickness graft can be an effective treatment for these

4 These indicators are listed respective of prevalence for 2010 cornea grafts according to EBAA data.
diseases, but outcomes with full-thickness transplants may not be optimal in measures of patient recovery time, resulting tectonic strength of the eye, or post-operative visual clarity.\(^5\)

Much of the innovation in corneal surgeries comes from academic research centers. Research centers treat the bulk of challenging corneal disease cases and serve to advance the leading edge of medicine. In comparison to research hubs, ASCs make standard treatments accessible to more broad populations of patients. CMS has structured awards to physicians and facilities that reflect these two objectives—treating expensive, challenging cases while maintaining affordability, efficiency, and access for more general cases.

The learning curve to proficiency to perform endothelial keratoplasty (EK) procedures is steep. Lamellar procedures are technically more difficult to perform than full-thickness grafts. However, because of superior outcomes for patients and the increasing demographic of likely candidate groups, EK procedures have become more widely used. According to data collected by the EBAA, the share of EK among all keratoplasty procedures in the U.S. grew at an annual rate of 10% from 2007 to 2011.

<table>
<thead>
<tr>
<th>Table 1: Increasing use of endothelial tissue grafting</th>
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<tr>
<td>Growth in Keratoplasty Procedures, 2007-2011</td>
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<td></td>
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<tr>
<td>Keratoplasty overall</td>
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<td>Endothelial keratoplasty</td>
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Source: Eye Bank Association of America Statistical Reports 2007-2011

In recent years, adoption of EK procedures has increased at nearly three times the rate of keratoplasty in general. Cornea transplants have been increasing overall, and much of the growth has been taking place in EK.

**REIMBURSEMENT OF ADVANCED PROCEDURES**

Innovations in surgical procedures are not always embraced during the reimbursement process, particularly with the limitations of standard procedural coding. Improvements in cornea surgery are no different. Changes in operating room time required, equipment used, advanced preparation, etc. that may make an innovative corneal graft procedure more expensive are not captured in current procedural coding standards.

Consider, for example, two new procedural codes for 2012 will allow IntraLase-Enabled Keratoplasty (IEK) procedures to be reimbursed by Medicare. This advanced procedure has been practiced for several years but practitioners had been unable to claim reimbursement for the laser-cutting step in the

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procedure. Before 2012, most IEK procedures were likely reimbursed at the rate of traditional PK procedures,\(^6\) and so the added cost of femtosecond laser preparation went uncompensated.

**OBSERVATIONS ON MEDICARE PAYMENTS**

Analysis of Medicare facilities claims for 2010, allowed us to generate a snapshot of ‘who, what, when, where, and how’ of corneal grafting.

*Corneal transplantation procedures for Medicare patients took place at ASCs slightly more frequently than at hospitals. ASCs represented 55% of procedures while hospitals made up the remaining procedures with 45%.*

*The most prevalent procedure among Medicare patients receiving corneal transplants was endothelial keratoplasty (EK), in which thin layers of corneal tissue are replaced in the patient’s eye. The majority of Medicare corneal transplant recipients—60%—received EK procedures, while 38% received full-thickness grafts. The data also includes a small number of keratoprostheses and anterior lamellar procedures.*

**MISSING CLAIMS FOR CORNEAL TISSUE**

Corneal tissue for transplant is reimbursed by Medicare as a “pass through” at reasonable cost. The data show that while Medicare paid for 74% of the nation’s corneal transplants only 33% of the corneal tissue used in Medicare procedures was billed back to Medicare. For the 30,765 procedures reimbursed through Medicare, only 10,065 corneal tissue items could be directly linked to Medicare administrative carrier records from the same year.

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\(^6\)It is impossible to distinguish between full-thickness graft procedures and femtosecond assisted procedures in the 2010 Medicare data because the laser preparation code was not yet accepted and billing a concurrent refractive procedure was not allowed.
It may be that corneal tissue buttons used in transplant procedures are reimbursed through channels other than Medicare and so do not show up in the data examined. Private payers, individuals, and other public payers may be paying for the corneal tissue itself while Medicare is reimbursing the surgical procedure. Contracts that bundle corneal tissue with procedure charges are frequently used in the private payer system, but are not used in traditional Medicare. Medicare Advantage (Part C) managed care plans absorb a significant number of Medicare enrollees in some markets and may mask some of the public payments that go to corneal transplantation. Managed care plans would bundle payment for both procedure and tissue fees, however. The payers for corneal tissue items not passed through the Medicare billing process remains a mystery.

**GAPS IN FACILITY CLAIMS**

Our analysis of Medicare claims data reveals inconsistencies in hospital billing practices. Often, hospital claims are missing an item for the tissue used during transplant surgery while ASCs generally bill completely. Approximately 45% of hospitals failed to fully bill for transplant procedures, leaving at least $8 million dollars—and potentially much more—unreimbursed due to missing corneal tissue items. The 45% of hospitals billing incorrectly made up 30% of all corneal transplants performed under Medicare.

The payment rates set by Medicare for ASC facilities are a function of cost reports submitted by hospitals. The CMS recalculates the ASC fee schedules and re-examines the cost sheets put together by hospitals. Due to the fact that ASC rates are dependent on these hospital cost reports, ASC and hospital reimbursement rates may be suffering because of gaps in hospitals’ cost sheets related to corneal transplantation and tissue.

As a result of under billing, corneal transplant surgeries may appear less expensive to healthcare policy makers than they really are particularly when examined through an episode of care lens. Reimbursement rates for both public and private payers are linked to Medicare claims submitted by hospitals. These claims include records of the costs that underpin each procedure.

Table 2: Endothelial grafts, for example, seem to be less expensive in hospitals than in ASCs

| Case: Medicare Reimbursement for Total Cost of EK Transplant Procedures and Tissue |
|-----------------------------------------------|-----------------|-----------------|
| Average total payment | Total lost to incorrect billing |
| Ambulatory surgical center facilities | $4,544 | $1 million |
| Hospital outpatient departments | $4,213 | $8 million |

The average reimbursement for similar procedures at ASCs was $4,544, while the average hospital claim came only to $4,213. Because hospitals frequently fail to include tissue pass through items on their Medicare reimbursement forms, the average rate of ASC reimbursement is greater than the average rate of hospital reimbursement. This observation is the opposite of what we expected.
This analysis does not include data from private payers or non-Medicare public payers; limitations of data prevent drawing conclusions about the entirety of domestic corneal transplantation. Considering these limitations, we believe that these reimbursement issues may be preventing some facilities from offering corneal transplantation procedures to Medicare patients, particularly in rural regions. ASC managers may choose to leave corneal transplants to the larger referral hospitals because the procedures are not reimbursed appropriately. Because many rural Americans depend on ASCs for treatment, we are concerned that some patients may be faced with access to care challenges.

ISSUES OF ACCESS TO CARE

SETTING THE BASELINE

Cataract surgery is the most frequently billed surgical procedure in Medicare. MedPAC, an independent fiscal advisor to the United States Congress and CMS, reports that simple cataract surgeries make up nearly 18% of all procedures reimbursed under Medicare at ambulatory surgical centers. ASCs allow patients to access common procedures— cataract phacoemulsification and intraocular lens implantation, for example —without a visit to a full-service hospital.

To understand the market of ophthalmic healthcare and the role of freestanding ASCs in providing care, it is important to recognize the enormous scale of cataract surgeries in the United States and specifically among Medicare beneficiaries. In 2010, more than 3.1 million cataract surgeries were done for Medicare-enrolled Americans for a total cost to the public payer system in excess of $3.3 billion. In terms of the numbers of procedures benefitting Medicare enrollees, the 2010 need for cataract surgery was approximately seventy times greater than the total number of corneal transplants done in the same year, according to our analysis. The fact that cataract removal is the most common procedure in all of ophthalmology implies that the procedure is widely accessible.

The accessibility of cataract procedures sets the baseline for patient access to ophthalmic surgery in general. As a benchmark for other ophthalmic procedures, none would be more accessible than cataract removal.

Charting cataract surgeries is a useful way to illustrate patient access to surgical care in different location around the country. We created the following map to show this.

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7A thorough analysis by the Medicare Payment Advisory Commission of expenditures in ASC settings was commissioned by Congress. This report also recommended requiring reporting of cost data along with Medicare claims from ASCs. MedPAC. “Report to the Congress: Medicare Payment Policy” Chapter 5, March 2012, accessible via http://www.medpac.gov/chapters/Mar12_Ch05.pdf
Density of Cataract Procedures in the Continental United States

Figure 3: Cataract procedures across the countries were provided at 4,020 facilities. Source: Medicare facilities claims 2010

ACCESS TO CORNEAL CARE

Corneal transplant surgeries are a small but significant niche in ophthalmology. These procedures are unique in the field for two reasons.

1. Corneal transplants always require buttons of donor tissue. This component of the procedure is provided by a tissue donor and prepared by an eye bank with a customized process for every surgical procedure. A supply of quality tissue is protected, at least for Medicare providers, by direct pass through reimbursement at invoice value for safe processing and transportation of donor tissue.

2. A large number of corneal transplants are directly tied to a corneal edema resulting from a cataract surgery. For patients with a high likelihood of requiring an endothelial corneal graft post-cataract removal, some practices recommend combining both a cataract removal and cornea transplant simultaneously. These concurrent procedures are probably advantageous for patients and definitely are cost saving for Medicare.8

8 When cataract removal, intraocular lens implantation, and corneal endothelial graft are combined, the procedure is referred to as a ‘corneal triple.’ The concurrence of these three procedures allows a patient at risk of endothelial failure secondary to cataract surgery to receive a more comprehensive treatment and potentially shorter time to recovery. Reimbursement rules pay 100% for the highest value procedure and at 50% ration for each remaining procedure done at the same time.
We compared the types of transplant procedures performed for Medicare patients at different facilities paying particular attention to how frequently the facility performed endothelial keratoplasty procedures. Most facilities performed both EK and full-thickness procedures. We found distinct regional variations in the relative frequencies of EK grafts among all corneal transplant procedures.\textsuperscript{9}

The type of cornea graft procedure is important because EK often offers better outcomes for patients with endothelial dysfunction compared to full-thickness transplants, even though the procedure is technically challenging. Particularly for endothelial failure—the majority of Medicare-paid transplant surgeries\textsuperscript{10}—EK often offers an option for better outcomes over PK along a number of measures.

What we noticed is that the rate of EK among all corneal transplants is seemingly highly dependent on the proximity to prominent research institutions that work to advance corneal transplant surgical technique. The findings of this forthcoming study are preliminary, but the initial results suggest that corneal transplant technique is slow to move out of the academic hospital context to the practices of mainstream ophthalmology. ASCs may be referring complex cases to research institutions, but as is evident in the following map, the hospitals doing the majority of endothelial transplant cases may be very far away, or in another state. This may make appropriate care for corneal disease inaccessible for some Medicare enrollees.

\textbf{Frequency of EK Procedures among Medicare Transplants in the Continental United States}

![Frequency of EK Procedures among Medicare Transplants in the Continental United States](image_url)

\textit{Figure 4: Charting the frequency of endothelial keratoplasty}

\textsuperscript{9} Some of this variation is due to the demographics of the patient population within each region. We expect that regions with patients of greater average age would have higher relative frequencies of EK transplant procedures, neglecting all other variable factors.

\textsuperscript{10}EK may also make up the overall majority of corneal transplants done in 2012.
CONCLUSIONS AND SOLUTIONS

Corneal surgeons are now operating in the context of healthcare reform and a rapidly increasing Medicare patient load. In the era of healthcare reform, introduced most recently and with great impact, by the Affordable Care Act, all provider costs will be scrutinized. Despite the small niche of corneal grafts within a much larger pool of cataract surgeries, corneal transplants will become an area of focus for cost and quality managers.

(1) We fear that the movement to advance cost efficiency will base expectations of the costs of corneal transplantation on regional averages distorted by hospital cost reports that fail to account for corneal tissue items. Standard practice is for hospitals to receive a higher rate of reimbursement than ASCs because of the higher overhead associated with complex and non-reimbursable cases. For an episode of care for a corneal transplant in Medicare, however, the total payment is reversed.

(2) We believe that the clustering of EK procedures near research centers may partly be due to shortcomings in continuing education programs at least in 2010. Providing continuing education to a broader group of corneal surgeons would, in our opinion, be the first step in correcting any issues of patient access to EK and furthering innovations in EK.

MEDICARE BACKGROUND AND REFERRALS

Medicare is the largest single payer for healthcare services in the United States. Americans of eligible age or special status, such as kidney disease requiring dialysis or disability, may choose to enroll in Medicare for partial or comprehensive coverage of their treatment needs.

The Centers for Medicare and Medicaid Services determines policies for the four categories of Medicare coverage:

Table 3: Medicare coverage options

<table>
<thead>
<tr>
<th>Segment</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>Part A</td>
<td>Hospital insurance</td>
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<tr>
<td>Part B</td>
<td>Medical insurance</td>
</tr>
<tr>
<td>Part C</td>
<td>Private managed care plans (Medicare Advantage)</td>
</tr>
<tr>
<td>Part D</td>
<td>Prescription drug benefits</td>
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</tbody>
</table>

Corneal transplant procedures are outpatient surgeries and are most frequently claimed under the medical insurance of Medicare Part B. In emergency cases and rare, complex cases a corneal graft will be required for an inpatient hospital stay; however, we assume that the vast majority of corneal transplants are performed in outpatient settings. Providers—the facilities hosting and the physicians performing outpatient surgical procedures—submit claims for service to Medicare administrative...
Medicare contractors (MACs), the private clearinghouses which adjust and verify claims for reimbursement through Medicare.

Medicare is most often the primary payer for enrollee’s procedures. Varieties of Medigap supplemental insurance are available in most states to share the costs of care beyond what is paid by Medicare including expanded coverage of services and reductions to patients’ out of pocket expenses.

**MEDICARE FACILITIES**

Ambulatory Surgical Centers (ASCs) play a significant role in delivering outpatient care, particularly in ophthalmology. The Medicare reimbursement process treats hospitals and ASCs differently. Reimbursement rates and billing procedures are vastly different under Medicare for ASCs and for hospitals. Hospitals are required to submit information about costs along with their charges for services. ASCs currently do not include cost information on their claims for reimbursement.

When the ASC payments system was revised in 2007, the forecast budget included payments to ASC facilities at 65% of hospital outpatient rates. For 2012, ASCs can expect to be compensated at 58% the level of large hospitals in accordance with CMS policy. This rate is variable, but hovers consistently around 60% from year to year as CMS readjusts the share of the Medicare budget separately allotted to ASCs and to hospitals. Division of resources is based on the assumption that hospitals take on the most resource-intensive cases and a greater share of uninsured patients. This system of payments encourages ASCs to refer complex cases and under-insured patients to hospitals for treatment.

The Centers for Medicare and Medicaid Services released the final rule governing ASC and hospital payments for 2013 setting the ASC payment rate at 56%, a ration 11% less than the initial budget forecast.
PROCEDURE CODING
Billing departments use Current Procedural Terminology (CPT)\textsuperscript{12} to encode surgical procedures for Medicare reimbursement. Other insurers insist on variants of procedural coding, but Medicare bill coding reflects the 'gold standard' for complete record keeping. For this study, we focused on the following CPT codes:

Table 4: Ophthalmology procedural codes examined in this research

<table>
<thead>
<tr>
<th>Description</th>
<th>CPT</th>
<th>Description</th>
<th>CPT</th>
</tr>
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<tbody>
<tr>
<td>Aphakic penetrating keratoplasty</td>
<td>65730</td>
<td>Endothelial keratoplasty</td>
<td>65756</td>
</tr>
<tr>
<td>Phakic penetrating keratoplasty</td>
<td>65750</td>
<td>Backbench prep. for endothelial pro.</td>
<td>65757</td>
</tr>
<tr>
<td>Pseudophakic penetrating keratoplasty</td>
<td>65755</td>
<td>Cataract removal, complex</td>
<td>66982</td>
</tr>
<tr>
<td>Anterior Lamellar keratoplasty</td>
<td>67510</td>
<td>Cataract removal, single stage</td>
<td>66984</td>
</tr>
<tr>
<td>Epikeratoplasty</td>
<td>65767</td>
<td>Keratoprosthesis</td>
<td>65770</td>
</tr>
<tr>
<td>Corneal tissue</td>
<td>V2785</td>
<td>Unspecified ophthalmic procedure</td>
<td>66999</td>
</tr>
</tbody>
</table>

LIMITATIONS AND BIAS OF MEDICARE DATA
This study is based on Medicare claims data that include the majority of Americans receiving corneal transplants every year. However, this data set is not complete. Patients from the following groups are not part of the data reviewed as part of this study:

- Those hospitalized for inpatient corneal transplants at hospitals
- Medicare enrollees choosing Medicare Advantage plans
- Beneficiaries of other public payer sources, such as CHIP, VA health services and state-based Medicaid
- Those entirely covered by private insurance plans or individuals paying out of pocket

Medicare coverage is available mainly to Americans older than 65. This presents a bias when studying the diseases indicating corneal graft procedures. Fuchs' endothelial dystrophy and post-cataract surgery edema patients are seemingly disproportionately represented in the Medicare population because of the age requirement for Medicare enrollment. The point at which a keratoconus patient needs a graft is less related to age, so we expect that indications for keratoconus are not oversampled in Medicare data.\textsuperscript{13}

\textsuperscript{12}The American Medical Association holds the copyright to CPT codes.
\textsuperscript{13}This statement is based on analysis of internal SightLife data. Given the large footprint of SightLife's service region, internal SightLife data may well approximate other parts of the country.
CONSEQUENCES

Distortion in Medicare reimbursement may affect healthcare delivery in two ways:

1. In future healthcare delivery models, the tissue pass through is far from guaranteed. Accountable care organizations may base fee structures on the total cost of corneal transplants rather than just the cost of procedures. Should corneal transplants in Medicare be done without the pass through, providers and suppliers will contend for their shares of the reimbursement fee for corneal transplantation. This tension will damage patient access to appropriate care and threaten the livelihood of non-profit eye banks. When outpatient surgery center managers plan for new services to offer patients, they may be passing by corneal transplants as an unfeasible offering.

2. In today’s private payer models, the fees paid to providers are based on hospitals’ reporting to CMS. Submissions to Medicare capture the charges, costs, and payments for procedures. This information influences the healthcare sectors beyond Medicare. When private insurers negotiate reimbursement contracts based on average costs of treatment according to hospital cost sheets, then the current baseline is too low.

Solutions to incorrect billing practice among hospital providers will come from corrective management of hospital billing departments. Surgical procedure coders should be careful to include the corneal tissue pass through with every corneal graft procedure. Essentially, the path to proper coding is through educating bill coders about current practices, diligently following best practices, and auditing the outcomes for reimbursement claims.

To aid hospitals in claiming proper reimbursement for corneal tissue, we are developing the best industry practices in structuring claims and negotiating with managed care organizations. Get in touch with the authors or visit www.sightlife.org/research for more information.
ABOUT THE RESEARCH

SightLife is an eye bank and global health organization headquartered in Seattle, Washington with locations in California and India. We undertook this project in order to understand the issues facing those suffering from corneal blindness in the United States. Along with our global programs building capacity among the world’s developing eye banks, we advocate for the elimination of corneal blindness worldwide.

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Rusty has dedicated his career in eye banking to increasing access to the highest quality corneal tissue for transplant. Under his leadership as California Regional Director, the region more than doubled the annual volume of corneal tissue available to surgeons. Prior to working at SightLife, Rusty was the Vice President for the Eye Bank Association of America (EBAA) as well as serving on the Board of Directors of Donate Life America and the faculty of the DHHS Health Services Resources Administration’s Organ Donation and Transplantation Breakthrough Collaborative.

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