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Financial Implications Associated with Laboratories Performing Laboratory Developed Tests For Medicare and Commercial Patients

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FINANCIAL IMPLICATIONS ASSOCIATED WITH LABORATORIES PERFORMING LABORATORY DEVELOPED TESTS FOR MEDICARE AND COMMERCIAL PATIENTS

BY

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A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
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Abstract of Doctoral Project Presented to the
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Degree of Doctor of Health Administration

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Chairperson: Daniel L. Brinton, PhD
Committee: Kit. N. Simpson, PhD
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Objective: To quantify missed reimbursements associated with specific CPT codes for Laboratory Developed Tests (LDTs) via polymerase chain reaction (PCR) in the United States during 2021.

Study Design: Quantitative, retrospective observational study to identify the dollar amount of missed reimbursements associated with 19 specific CPT codes billed for Medicare patients who had LDTs performed via PCR in the United States in 2021.

Data Sources: 19 specific CPT codes from Medicare and Commercial patients with LDT PCR testing performed using 2021 Meridian MarketScan data.

Key Results: Medicare represented 1.7% of the sample size with a potential lost revenue of $1M where Medicare reimbursed higher per CPT code when claims were paid, but had a higher zero dollar payment rate when compared to Commercial claims for the same 19 CPT codes.

Key Words: Laboratory Developed Tests, Polymerase Chain Reaction, Reimbursement

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CPT	Current Procedural Terminology
FDA	Food and Drug Administration
LDT	Laboratory Developed Test
PCR	Polymerase Chain Reaction

CHAPTER 1 INTRODUCTION

Background and Need

The healthcare system is reliant on laboratories to perform essential diagnostic testing to assist clinicians with patient care. Laboratory testing offers standard and customized testing protocols to ensure there is continuity of care across the healthcare continuum.

Laboratory Developed Tests (LDTs) are a segment of molecular diagnostic testing, which allows for laboratories to customize testing to meet the needs of their clients and patients, when compared to standardized testing methodologies approved by the FDA. LDTs undergo a process to create, which ensures accuracy of such testing and compliance with regulatory guidelines at the state and national level. Relative to FDA approved testing and LDTs, automation and resource reliance can contribute to LDTs methodology to be more cost effective and timely to perform, per sample. Understanding the reimbursement challenges surrounding LDTs plays a crucial role with the sustainability of laboratories' abilities to perform such testing, long term. There are significant disparities across LDT CPT code allowables and reimbursements, which limit the longevity of offering adequate testing, specific to patient needs.

SUMMARY OF LITERATURE

A literature review was performed to identify the current use of a set of laboratory tests, known as LDTs and the reimbursement limitations for laboratories performing such testing. While there is limited research on LDTs and Medicare reimbursement data, a study performed by Tennant & Byers (2020) focusing on the reimbursements by

Medicare on Next Generation Sequencing (NGS) testing revealed Medicare did not reimburse the two analyzed CPT codes, when compared to Commercial and Medicaid claims for the same procedural codes. There is skepticism surrounding the accuracy of LDTs which can influence the reimbursement challenges faced; however, a study performed by Kim et. al (2018) compared three oncology analytes using two different testing methodologies, one FDA approved and one LDT. The results of this study yielded a greater than 97% accuracy, which would suggest LDTs are at least as good as FDA approved testing.

Literature review findings indicate there is limited data to investigate a correlation between lost revenue associated with LDTs, based on the CMS, Clinical Laboratory Fee Schedule; however, there is research tangentially related to the development of LDTs and Medicare reimbursement.

AIM

This retrospective, observational study is designed to assess the potential revenue loss, as well as reimbursement discrepancies between Medicare and Commercial payers. The study will evaluate the total lost revenue incurred by laboratories performing LDTs on Medicare adjudicated claims in 2021, in addition to a correlational analysis between Medicare and Commercial payers for claims associated with LDTs. Both analyses will utilize a list of 19 CPT codes, identified to be billed with claims specific to diagnostic testing pertaining to LDTs.

The insights gained from this study have the potential to influence future legislation surrounding reimbursements for LDTs. This study will surface the potential

implications of laboratories performing LDTs across the United States, in an effort to assess financial disparities between payers, thus positively impacting reimbursements for such testing. Without adequate reimbursements from payers, it is not sustainable for laboratories to perform this needed testing.

CHAPTER 2 LITERATURE REVIEW

Overview

Laboratories are an essential component to healthcare systems across the globe. Laboratory tests help clinicians diagnose medical conditions, assess treatment protocols and manage disease (U.S. National Library of Medicine, 2017). Laboratory testing ranges in complexity, which affects the type of credentialing, staffing and equipment needed to process certain tests. Testing categorized as high complexity, includes laboratory developed tests (LDTs) which allow the lab to meet the needs of the clients and patients they serve, by customizing the pathogens being analyzed. Despite the need for LDTs, there are limitations on reimbursement of such testing by Medicare. LDTs are not FDA approved tests and therefore pose significant challenges to laboratories when submitting claims for payment by Medicare.

Laboratory Developed Tests

Background

Laboratory medicine is an evolving sector in healthcare, where approximately 3.3 billion In Vitro Diagnostic tests (IVD) and 12,000 laboratories throughout the United States utilize laboratory developed tests (The Pew Charitable Trusts, 2021). *The World Health Organization (2020)* defines IVD tests as tests that can detect disease, conditions and infections through means of test tubes and similar equipment outside of the body. IVD is the broad terminology used to describe LDTs and other molecular diagnostic testing. As described by the Centers for Medicare & Medicaid Services (CMS) (2013) an LDT is defined by the FDA as a "…diagnostic test that is manufactured by and used

within a single laboratory…", they are also referred to as "…in-house developed tests, or 'home brew' tests" (p.1). Such testing allows laboratories to customize panels by adding pathogens that are relevant to meet the needs of the clients and patients they serve.

Legal Requirements to Develop

In order for laboratories to perform LDTs, they must comply with regulating bodies including Clinical Laboratory Improvement Amendments (CLIA), Commission on Office Laboratory Accreditation (COLA), College of American Pathologists (CAP) and Joint Commission, respectively. LDTs are regulated by the FDA under the Medical Device Amendment (MDA) of 1976, which assures the safety and effectiveness of medical devices, (Center for Devices and Radiological Health, 2023). Currently, LDTs are covered through the general enforcement discretion approach just as other LDTs; however, on October 3, 2023, the United States government released a proposed rule to ensure IVDs and LDTs should be considered devices under the Federal Food, Drug and Cosmetic Act (FD&C Act) even when the manufacturer is the laboratory performing the testing (Chiodini, 2023). This policy would result in a phase out of the current general enforcement discretion methodology for such testing, which will cause challenges surrounding the creation and utilization of LDTs for laboratories, to include current LDT use.

Currently, laboratories licensed as a high complexity laboratory are the only laboratories that can compliantly develop and perform LDTs. High complexity laboratories fall under the nonwaived testing terminology, as described by the CDC (2018) and must too be licensed through CLIA to perform such testing. According to the

CDC (2018), nonwaived testing includes tests developed by the laboratory or have been modified from the original manufacturer's instructions. The CDC (2018) describes the significance of high complexity testing as testing requiring different proficiency testing, quality control and assessment, and personnel requirements when compared to moderate complexity and waived CLIA testing, due to altering the manufacturer's methodology on how the testing was originally designed to be performed. Despite these pre-requirements, according to CMS (2010), there are concerns about the quality of LDTs and the validations being performed on them. CMS (2018) further explains these concerns arise from claims that lack evidence or appropriate controls, subsequently yielding erroneous results. While the FDA re-evaluated the capabilities and limitations of LDTs, relative to FDA approved testing in 2017, there were still concerns about the ability to uniformly rely on all tests offered for clinical use. Despite the FDA's concerns about accuracy surrounding LDTs, the CDC (2021) recognized even though CLIA waived tests are unaltered from the manufacturer when performing laboratory testing, this testing methodology is still not error-proof. Regardless if testing is created by a laboratory or being performed to the manufacturer's specs, there is still a degree of error.

Performance Comparison of Laboratory Testing

A comparative study performed by Kim et al. (2018) examined results for three oncology analytes B-Raf proto-oncogene, serine/threonine kinase (BRAF), Epidermal Growth Factor Receptor (EGFR) and Kirsten rat sarcoma virus (KRAS) testing on both an LDT platform and FDA approved assay. Proficiency testing is required to ensure compliance with regulatory guidelines. These three analytes have an existing FDA

approved assay and an LDT in place where both could be performed simultaneously to compare the results. Specifically, these three tests have proficiency testing, available through the College of American Pathologists (CAP), which is needed to ensure accuracy of testing performed amongst laboratories. CAP samples are provided to the laboratory needing to compare their results to known positive samples to confirm the laboratory's platforms are performing the way they should, thus ensuring accurate results. This validation process is standard protocol for any testing being performed in a laboratory. To ensure accuracy of molecular diagnostic testing created by the use of LDTs, the validation process assesses performance characteristics to include, but not limited to, accuracy, precision, analytic sensitivity, analytic specificity, reportable range, reference range, and any other characteristics that are necessary to the test being performed (Gargis et al., 2016). Including these measurable parameters, among others as needed to ensure accuracy of such created tests, enforces the validity and reliability of the yielded results. If a testing protocol fails validation, the test is not permitted to move into circulation for live patient samples. The process to continue the validation will ensue until successful validation has been achieved. The study concluded, among the three different analytes run on the two different methodologies, they all yielded an accuracy of greater than 97% which suggests LDTs are at least as accurate as FDA approved testing methodologies.

According to Genzen (2019), LDTs have been developed by laboratories to meet the unmet analytical or clinical needs of the patients. Genzen (2019) further explains limitations surrounding FDA approved assays and the equipment requirements for testing. Rather than purchasing new laboratory equipment to run FDA approved assays,

laboratories resort to developing LDTs on the instrumentation currently being utilized in their laboratory, which allows for higher throughput of sample volume with more automation.

Other FDA Approved Methodologies, *BioFire*

FDA approved methodologies, such as the *BioFire* require more hands-on time to prepare and load each sample onto the machine. *BioFire* instrumentation among other platforms has panels considered as CLIA-waived tests which means these tests were determined by the CDC or FDA to be so simple, that the risk of error was minimal (*CMS, n.d.).* This alone indicates the challenges of the process which inhibits laboratories to meet the needs of the clients and patients being served. This type of approach is beneficial as a point of care test to be performed at a doctor's office because these types of tests are simple with a low risk for incorrect results (CDC, 2018). The *BioFire* requires each sample to be manually set up by injecting the hydration solution into the pouch containing the reagents based on the test being performed and then pipetting the patient sample in the buffer tube to be injected into the pouch for processing. Each pouch has a barcode which tells the instrument what tests are being performed for the sample, all patient information then needs to be input into the system. This process must be completed for every sample being run on the machine, if there is a single patient needing to have two assays run, this process will be completed manually twice for the same patient. While this process takes one hour from the time the machine starts, to when a result yields, this produces a single result in one hour which is not conducive for high volume laboratories. Additionally, this testing platform does not allow for flexibility with

the organisms being tested. The panels in this case, are premade and the laboratory will need to run the entire panel even if the client only wants to test for one organism on it, thus resulting in a financial loss for that test. Laboratories can only bill for tests that were ordered, not tests that were run which makes LDTs more appealing to laboratories so they can run exactly what the clients are ordering. Unlike the *BioFire*, LDTs are designed to accommodate hundreds and thousands of samples within just hours of processing time with more automation, resulting in less hands-on time and a lower cost per sample. To accommodate a high-volume laboratory that meets the requirements as a high complexity laboratory, an LDT can be developed using a 384 well plate which means up to 384 samples can be processed in a single run. The number is variable depending on the methodology of the testing since the number of organisms being tested for will determine the number of controls needed for each run. This single plate with up to 384 patient samples would be multiplexed, so each individual well would have all organisms being tested for, along with the patient sample. The 384 well plate will go through a process to extract the patient samples, add all master mixes, controls and reagents to each well then be placed on an instrument for amplification which will yield the final graphs with the patient results. Depending on instruments being used and the protocol developed for the LDT, this process can take as little as 6 hours for up to 384 patient samples. High complexity laboratories specialize in processing LDTs, where licensed medical professionals who underwent additional schooling and training to be qualified to perform such level of testing is performing the testing. This methodology, unlike the *BioFire*, is not something anyone can run. While there are other FDA approved platforms, LDTs

would be preferred due to them being more efficient, economical and customizable based on the populations being served.

PCR Testing

Laboratories are already running molecular testing via Polymerase Chain Reaction (PCR), so to bring on additional equipment to comply with FDA approved assays in an effort to get reimbursed by Medicare causes concerns with physical space, upfront costs for equipment acquisition, costs to train on new equipment, increased hands-on time for new instrumentation, changes in throughput and turnaround time, as well as reagent costs per sample.

Medicare and LDTs

While LDTs are commonly used to personalize medicine for each patient receiving testing, there have been significant challenges surrounding Medicare reimbursements for LDTs which poses threats to the longevity of needed testing. There are stipulations to ensure adequate reimbursement by Medicare for testing performed; however, there is limited reimbursement by Medicare for LDTs since LDTs are not considered FDA approved tests.

Medicare Overview

According to *medicare.gov*, this federally funded insurance program is for people who are 65 or older, certain young individuals with disabilities and people with end stage renal disease. *Medicare enrollment numbers* (2023) as of March 2023, over 65,000,000 people were enrolled in Medicare which was an increase of about 100,000 since September of 2022. *Figure 1*, composed from the *cms.gov* database, shows the Medicare

Enrollment numbers steadily increasing, resulting in a 1.61% increase from June 2022 to June 2023 which equates to an increase of over 1,000,000 enrollments. At this rate of change, in June 2023, there were more than 66,000,000 people in the United States enrolled in Medicare. Over the years, there is a steady increase of almost 2% in Medicare enrollments throughout the United States. Since 2020, there has been no decline in numbers, which would indicate as time goes on, these numbers will continue to rise.

Medicare is comprised of four parts: Part A, Part B, Part C and Part D. *CMS.gov* explains these components as follows, Part A includes hospital coverage, Part B is supplementary medical insurance, Part C is the Medicare Advantage program and Part D covers prescription drugs. Medicare Parts A and B form the original Medicare program which focused on the fee-for-service approach. Laboratory testing payment falls under Medicare Part B, which is part of the medical insurance component.

CMS Laboratory Reimbursement

CMS releases fee schedules which represent a complete list of CPT codes used by Medicare to reimburse providers and suppliers for services rendered. The fee schedules include the CPT codes for the services performed, needing to be billed for both technical and professional services, along with the respective maximum allowable reimbursement by procedure. The maximum allowable identifies the most a payer will reimburse on a particular CPT code when submitted on a claim; this allowable varies by payer.

Medicare Impact on Laboratory Developed Tests

LDTs allow for tailored testing to meet the needs of the clients and patients being tested. Just like any fee for service, receiving payment for the services rendered ensures

businesses can continue to operate. As such, it is important laboratories are paid adequately for all services performed; however, Medicare has stipulations which limit reimbursements for LDTs in the United States. Currently LDTs are not considered FDA approved tests, which negatively impacts reimbursements from Medicare. In 2022, Medicare alone comprised of 18.7% of the United States population covered by insurance which is second behind Medicaid at 18.8% (Santos et al., 2023, p.2). As Medicare numbers continue to rise, laboratories' financials are further jeopardized due to reimbursements for LDTs being limited for this patient population. Every year the Medicare use increases which causes concern for laboratories as they continue to perform testing run on LDTs, ordered by providers with minimal to no reimbursement from Medicare.

Reimbursements for LDTs negatively impact the laboratory industry, which is an integral part of the health system, providing critical diagnostic testing for patients.

Current Literature

There are many articles that are tangentially related to the development of LDTs and Medicare reimbursement; however, no existing literature analyzes the financial impact Medicare has on reimbursement of LDTs throughout the United States. Among the variety of laboratory tests offered, there is a category referred to as next generation sequencing (NGS). NGS testing is a high complexity test that uses technology to assist with the sequencing of DNA and RNA to detect variant and mutation abnormalities (Dahui, 2019). A study completed by Tennant & Byers (2020) analyzed claims for two NGS CPT codes, where testing was performed by a single laboratory. Among the payers

reviewed, Medicare did not reimburse for any of the claims submitted, compared to commercial payers and Medicaid patients. While this study focuses on NGS testing on an isolated sample group, it supports the claim surrounding Medicare reimbursement challenges. Mantovani et al. (2023) reviewed current and prospective reimbursement parameters for software based IVDs throughout the United States, Germany, France, United Kingdom and Australia. Reimbursement challenges in the laboratory field are widely experienced across the globe, but there is no known correlation between LDTs and Medicare reimbursements in the United States.

Summary

While LDTs are performed throughout the United States, research has not yet quantified the lost revenue from LDTs in the Medicare population. There are limitations with current research and data on the financial deficits associated with LDT reimbursements. If legislation and CMS guidelines are not re-evaluated, laboratories performing LDTs will be challenged to continue such testing, due to Medicare reimbursement limitations. Medicare enrollment numbers are continuing to increase, which will only lead to an increase in revenue losses associated with laboratories performing LDTs. Patients are always going to need diagnostic testing, and providers will continue to order necessary testing for patients, regardless of the patient's insurance status. Evaluating the losses to laboratories performing LDTs for patients with Medicare can influence future legislative changes, by ensuring adequate reimbursements to keep LDTs in circulation.

CHAPTER 3 METHODS

Problem

Laboratories perform essential testing, needed for adequate patient care; however, there are associated costs to the laboratory for performing such testing. There are limitations surrounding Medicare reimbursements for certain CPT codes, associated with LDTs. Due to costs incurred from performing laboratory testing, it is imperative laboratories are reimbursed by payors to ensure they can continue performing testing ordered by clinicians.

Research Question

Question 1

What is the total lost revenue incurred by laboratories performing LDTs on Medicare adjudicated claims in 2021 for 19 individual CPT codes, specific to LDTs?

Question 2

What is the median reimbursement collected by laboratories performing LDTs on Medicare patients, compared to Commercial payer patient claims, adjudicated in 2021 by CPT code, specific to LDTs?

Hypotheses

Question 1 Hypotheses

H_0- Laboratories incur no revenue deficits from processing laboratory developed tests for Medicare patients.

H_1- Laboratories incur revenue losses from processing laboratory developed tests for Medicare patients.

Question 2 Hypotheses

H_0- Laboratories incur no revenue deficits from processing laboratory developed tests for Medicare patients, compared to Commercial payers.

H_1- Laboratories incur revenue losses from processing laboratory developed tests for Medicare patients, compared to Commercial payers.

Study Objectives

The objective of this study is to quantify missed reimbursements associated with specific CPT codes for LDTs via polymerase chain reaction (PCR) in the United States during 2021. A series of common CPT codes to include: 87481, 87486, 87491, 87498, 87502, 87511, 87529, 87563, 87581, 87591, 87633, 87634, 87640, 87641, 87651, 87653, 87661, 87798, 87801 that were billed for Medicare and Commercial patients who had LDTs performed via PCR will be extracted with its associated billables from 2021 Medicare and Commercial MarketScan data. *Table 1* outlines the 19 CPT codes with the respective CPT Code Description as described by CMS (2023). The charges associated with zero-dollar payments will be compiled by CPT code for a total of lost revenue by CPT code, in addition to the sum of all 19 CPT codes for Medicare and Commercial claims, respectively. To further evaluate the deficits concerning existing reimbursements between the 19 CPT codes amongst payers, this study will evaluate the total median reimbursement value associated with each CPT code, comparing Medicare and Commercial payers.

Data Sourcing

The study utilizes 2021 Meridian MarketScan data, for both Medicare and Commercial payers across the United States. MarketScan data is comprised of six databases with deidentified data including, Commercial (CCAE), Medicare (MDCR), Benefit Plan Design (BPD), Health and Productivity Management (HPM), Medicaid and Lab. This study will focus on the data within the Medicare and Commercial databases, where Medicare includes primarily fee for service plan data and only Medicare-eligible retirees with employer-sponsored Medicare Supplemental and Medicare Advantage plans. Similarly, the Commercial database contains data from those who are not eligible for Medicare to include active employees, early retirees, COBRA enrolls and dependents insured by employer sponsored plans (Commercial Database & Medicare Database User Guide Data Year 2021 2022). All billable charges for Medicare and Commercial patients are broken down by the 19 CPT codes identified to be associated with PCR, LDTs. The population being analyzed includes all Medicare and Commercial patients having a claim adjudicated in 2021 with the 19 associated CPT codes.

Study Design

The study encompasses a quantitative, retrospective observational approach to identify the dollar amount of missed reimbursements associated with 19 specific CPT codes billed for Medicare patients who had LDTs performed via PCR, utilizing 2021 Medicare and Commercial MarketScan data. Any charge with a zero-dollar payment will be added together with the Medicare allowable, from the 2021 Clinical Laboratory Fee Schedule by CMS, to provide the total lost revenue. The 2021 Clinical Laboratory Fee

Schedule identifies all eligible CPT codes with their respective Medicare allowable. The CPT codes included in this analysis are PCR CPT codes found in respiratory, urinary tract infection, women's health and sexually transmitted disease LDT panels. Each LDT created has its own set of CPT codes which can vary from LDT to LDT and therefore, this is not a comprehensive list of all PCR CPT codes, but a list reflective of a single reference laboratory processing these tests utilizing LDTs for diagnostic analysis.

Statistical Analysis

A summary table will be utilized to depict the number of zero-dollar payments for each of the 19 CPT codes identified, compared to the Medicare allowable for each. While evaluating the zero-dollar payments, the charges will be verified to ensure zero-dollar bills were not paid at a later date by Medicare due to refiling; any claim falling into this category with be excluded from the study. Once compiled, the total missed reimbursements will be evaluated by CPT code and in totality for a comprehensive value in missed reimbursements. This value will provide a total missed reimbursed amount, as it correlates to the amount Medicare patients receiving testing categorized by any of the 19 CPT codes associated with PCR, LDTs. As an exploratory aim we will examine demographic differences between paid and not paid claims using univariate statistics. This study will also provide a parenthetical explanation on the median reimbursements collected on Medicare claims compared to Commercial payer claims. This will be achieved by compiling the total reimbursements associated with Medicare and Commercial claims, by CPT code, respectively where the median of both totals will be analyzed. All analyses will be performed using SAS 9.4 (Cary, NC). All revenue will be

inflation adjusted to 2023 dollars using US Bureau of labor stats consumer price index (Databases, tables & calculators by subject 2024).

Protection of Human Subjects

This study uses aggregated, deidentified data, thus is exempt.

Study Limitations

This study is not inclusive of all CPT codes associated with LDTs and therefore is not generalizable amongst all LDT billables. The data in this study lacks granularity due to the exclusion of denial codes from the claims analyzed and all claims associated with the 19 CPT codes were grouped together based on payer. If denial codes were included, this study would be more accurate with reimbursement payer data. It would be beneficial to assess the distribution of denials by payer; however, current research does not support this analysis.

Summary

This retrospective study will evaluate the revenue losses for laboratories that performed LDTs for Medicare insured patients, compared to Commercial payers during fiscal year 2021 throughout the United States. While analyzing historical data, this will allow for future projections of potential revenue losses to laboratories throughout the United States, as it pertains to LDT Medicare reimbursements.

CHAPTER 4 MANUSCRIPT

Introduction

Laboratory testing is an integral component to the healthcare continuum, allowing for varying analyses to be completed, providing insight on the patient's bodily performance. Such testing includes both standard and customized testing protocols to ensure continuity of care.

Laboratory Developed Tests (LDTs) are a segment of molecular diagnostic testing, which allows for laboratories to customize testing to meet the needs of their clients and patients, when compared to standardized testing methodologies approved by the FDA. LDTs undergo a process to create, which ensures accuracy of such testing and compliance with regulatory guidelines at the state and national level. Relative to FDA approved testing and LDTs, automation and resource reliance can contribute to LDTs methodology to be more cost effective and timely to perform, per sample. Understanding the reimbursement challenges surrounding LDTs plays a crucial role with the sustainability of laboratories' abilities to perform such testing, long term. There are significant disparities across LDT CPT code allowables and reimbursements, which limit the longevity of offering adequate testing, specific to patient needs.

Background

Laboratories perform essential testing needed for adequate patient care. There are limitations surrounding Medicare reimbursement for certain CPT codes associated with LDTs which impact the laboratories' ability to continue processing tests.

A literature review was performed to identify the current use of LDTs and the reimbursement limitations for laboratories performing such testing. Literature review findings indicate there is limited data to investigate a correlation between lost revenue associated with LDTs, based on the CMS, Clinical Laboratory Fee Schedule; however, there is research tangentially related to the development of LDTs and Medicare reimbursement.

This retrospective, observational study is designed to assess the potential revenue loss, as well as reimbursement discrepancies between Medicare and Commercial payers. Throughout this study, we will analyze two questions to better understand the variance between reimbursements for 19 specific CPT codes across Medicare and Commercial payers. We will identify the total lost revenue incurred by laboratories performing LDTs on Medicare adjudicated claims in 2021, for 19 CPT codes, in addition to the Median reimbursement collected by laboratories performing LDTs on Medicare patients compared to Commercial payer claims for the same 19 CPT codes and reporting period.

Methods

Data Sourcing

Using deidentified, 2021 Meridian MarketScan data, this study will review claims for Medicare and Commercial payers across the United States. All billable charges for Medicare and Commercial patients are broken down by the 19, identified, CPT codes to be associated with PCR, LDT claims. This study will focus on the data within the Medicare and Commercial databases, where Medicare includes primarily fee for service plan data and only Medicare-eligible retirees with employer-sponsored Medicare

Supplemental and Medicare Advantage plans. Similarly, the Commercial database contains data from those who are not eligible for Medicare to include active employees, early retirees, COBRA enrolls and dependents insured by employer sponsored plans (Commercial Database & Medicare Database User Guide Data Year 2021 2022).

Study Design

The dollar amount of missed reimbursements associated with 19 specific CPT codes billed for Medicare patients who had LDTs performed via PCR, utilizing 2021 Medicare and Commercial MarketScan data will. Any charge with a zero-dollar payment will be added together with the Medicare allowable, from the 2021 Clinical Laboratory Fee Schedule by CMS, to provide the total lost revenue. The 2021 Clinical Laboratory Fee Schedule identifies all eligible CPT codes with their respective Medicare allowable. The CPT codes included in this analysis are PCR CPT codes found in respiratory, urinary tract infection, women's health and sexually transmitted disease LDT panels.

Statistical Analysis

A summary table will be utilized to depict the number of zero-dollar payments for each of the 19 CPT codes identified, compared to the Medicare allowable for each. While evaluating the zero-dollar payments, the charges will be verified to ensure zero-dollar bills were not paid at a later date by Medicare due to refiling; any claim falling into this category with be excluded from the study. Once compiled, the total missed reimbursements will be evaluated by CPT code and in totality for a comprehensive value in missed reimbursements. This value will provide a total missed reimbursed amount, as it correlates to the amount Medicare patients receiving testing categorized by any of the

19 CPT codes associated with PCR, LDTs. As an exploratory aim we will examine demographic differences between paid and not paid claims using univariate statistics. This study will also provide a parenthetical explanation on the median reimbursements collected on Medicare claims compared to Commercial payer claims. This will be achieved by compiling the total reimbursements associated with Medicare and Commercial claims, by CPT code, respectively where the median of both totals will be analyzed. All analyses will be performed using SAS 9.4 (Cary, NC). All revenue will be inflation adjusted to 2023 dollars using US Bureau of labor stats consumer price index (Databases, tables & calculators by subject 2024).

Results

The 2021 Medicare and Commercial MarketScan data were compiled in a series of summary tables to depict the variability between reimbursements across 19 CPT codes. This study analyzed 5,041,198 CPT code billables with claims including the 19 specific CPT codes, with Medicare representing 1.7% of the data set and Commercial payers, 98.3%. *Table 2* identifies the number of CPT codes not reimbursed by Medicare and Commercial payers, respectively.

Table 3 represents the percentage of zero dollar payments by Medicare compared to Commercial payers, with Medicare including a 19.1% zero dollar payment rate relative to Commercial payers at 6.0%, thus indicating Medicare claims for these CPT codes are about 3 times more likely to be reimbursed than Commercial claims for the same CPT codes. CPT code 87633 has the highest allowable per CMS and represents the highest percentage of labs not paid by Medicare.

Table 4 further analyzes the lost revenue, relative to the possible reimbursement amount per the CMS Clinical Laboratory fee schedule for this sample size, resulting in 25.4% of potential lost revenue on the Medicare CPT codes ($1,013,493.97), compared to 6.8% for Commercial payers ($14,030,555.67). Claims submitted with Medicare as the patient's insurance, lost 18.6% more potential revenue than Commercial payer claims. The total number of claims submitted to Commercial payers represent the majority of the data set at 4,956,341 (98.3%) with Medicare representing 84,767 (1.7%).

On average, Medicare is 48% more likely to reimburse higher per CPT code than Commercial payers. *Table 5* identifies the Medicare to Commercial payer difference with 74%, 14 out of 19 CPT codes billed to Medicare have a higher median reimbursement rate compared to the Commercial payers, where Medicare reimbursed less than Commercial payers, 5 out of 19 CPT codes, for 26% of the sample size. 5 out of 19 CPT codes yield a lower Medicare reimbursement rate when compared to the median reimbursement rate by payer. There is an outlier with CPT code, 87801 where the median Medicare reimbursement is greater than the allowable. This should also be noted in *Table 6* where the upper quartile for 4 out of 19 CPT Codes (87481, 87529, 87798 and 87801) are higher than the Medicare allowable, which indicates the highest typical reimbursement received for this dataset. *Table 5* indicates Commercial payers reimburse less than the CMS fee schedule. *Tables 6* and *7* represent similar information with reimbursement statistics per payer, by CPT code; however, the former is Medicare data where the latter is Commercial.

Discussion

For CPT codes associated with Medicare claims, with a median or upper quartile value greater than the CMS fee schedule (87481, 87529, 87798 and 87801), an assumption can be made whereby these claims had commercial insurance as primary and Medicare as secondary insurance. Each payer has their own allowable amount, which can differ from the Medicare allowable. When commercial insurance is primary and their allowable is higher than Medicare, Medicare will pay up to the amount of the higher allowable, so long as the difference does not exceed the Medicare allowable (American Psychiatric Association, 2014). In this case an example can be given where the primary insurance pays $100.40 toward 87801, with the primary insurance having an allowable of $140.40. The difference between what primary insurance paid and the primary insurance allowable, is less than the Medicare allowable, at $70.20. Medicare will come in and pay $40.00, so the procedure is fully reimbursed at the primary insurer's rate.

We should also consider the possibility of a higher reimbursement compared to the CMS fee schedule, a result of the provider not having a contract with Medicare. Per *CMS* (2023), if a provider is not contracted with Medicare, but submits a claim for reimbursement, Medicare is required to pay at no less than the amount to be paid under original Medicare. This is applicable to parts A and B only and since laboratory testing is covered under Medicare Part B, the rule would apply, thus indicating a possibility for higher reimbursement on these claims.

Commercial payers reimburse less than the CMS fee schedule; however, we should consider the fact, Commercial payers establish their own fee schedule,

independent of the CMS fee schedule. This analysis compares the data to the CMS fee schedule, due to the Medicare allowables being standardized, compared to Commercial payers varying by contract.

It is important to note, despite the lesser reimbursement from Commercial payers to the CMS fee schedule, the overall potential Medicare lost revenue is disproportionally higher than Commercial payers, relative to the sample size ratios. This is revenue needed to be collected by laboratories, as the expenses have already been incurred. Laboratories do not control what clinicians order; it is the laboratories' role to process what is ordered and bill accordingly. Physicians will continue to order laboratory testing, as they deem medically necessary for patient care and therefore, laboratories should be reimbursed adequately for processing these tests.

Table 1

CPT CODE	CPT CODE DESCRIPTION
87481	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CANDIDA SPECIES, AMPLIFIED PROBE TECHNIQUE
87486	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CHLAMYDIA PNEUMONIAE, AMPLIFIED PROBE TECHNIQUE
87491	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); CHLAMYDIA TRACHOMATIS, AMPLIFIED PROBE TECHNIQUE
87498	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); ENTEROVIRUS, AMPLIFIED PROBE TECHNIQUE, INCLUDES REVERSE TRANSCRIPTION WHEN PERFORMED
87502	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); INFLUENZA VIRUS, FOR MULTIPLE TYPES OR SUB-TYPES, INCLUDES MULTIPLEX REVERSE TRANSCRIPTION, WHEN PERFORMED, AND MULTIPLEX AMPLIFIED PROBE TECHNIQUE, FIRST 2 TYPES OR SUB-TYPES
87511	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); GARDNERELLA VAGINALIS, AMPLIFIED PROBE TECHNIQUE
87529	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); HERPES SIMPLEX VIRUS, AMPLIFIED PROBE TECHNIQUE
87563	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); MYCOPLASMA GENITALIUM, AMPLIFIED PROBE TECHNIQUE
87581	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); MYCOPLASMA PNEUMONIAE, AMPLIFIED PROBE TECHNIQUE
87591	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); NEISSERIA GONORRHOEAE, AMPLIFIED PROBE TECHNIQUE
87633	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); RESPIRATORY VIRUS (EG, ADENOVIRUS, INFLUENZA VIRUS, CORONAVIRUS, METAPNEUMOVIRUS, PARAINFLUENZA VIRUS,

	RESPIRATORY SYNCYTIAL VIRUS, RHINOVIRUS), INCLUDES MULTIPLEX REVERSE TRANSCRIPTION, WHEN PERFORMED, AND MULTIPLEX AMPLIFIED PROBE TECHNIQUE, MULTIPLE TYPES OR SUBTYPES, 12-25 TARGETS
87640	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); STAPHYLOCOCCUS AUREUS, AMPLIFIED PROBE TECHNIQUE
87641	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); STAPHYLOCOCCUS AUREUS, METHICILLIN RESISTANT, AMPLIFIED PROBE TECHNIQUE
87651	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); STREPTOCOCCUS, GROUP A, AMPLIFIED PROBE TECHNIQUE
87653	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); STREPTOCOCCUS, GROUP B, AMPLIFIED PROBE TECHNIQUE
87661	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA); TRICHOMONAS VAGINALIS, AMPLIFIED PROBE TECHNIQUE
87798	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA), NOT OTHERWISE SPECIFIED; AMPLIFIED PROBE TECHNIQUE, EACH ORGANISM
87801	INFECTIOUS AGENT DETECTION BY NUCLEIC ACID (DNA OR RNA), MULTIPLE ORGANISMS; AMPLIFIED PROBE(S) TECHNIQUE

Table 1: CPT code descriptions were sourced from CMS.gov, 2023.

Table 2

CPT Code	CMS FEE SCHEDULE 2021	# of labs not paid by Medicare	# of labs not paid by Commercial	TOTAL average lost revenue by Medicare	TOTAL average lost revenue by Commercial
87481	$ 35.09	438	1,437	$ 15,369.42	$ 50,424.33
87486	$ 35.09	593	5,864	$ 20,808.37	$ 205,767.76
87491	$ 35.09	1,147	82,000	$ 40,248.23	$ 2,877,380.00
87498	$ 35.09	39	362	$ 1,368.51	$ 12,702.58
87502	$ 95.80	1,068	10,274	$ 102,314.40	$ 984,249.20
87511	$ 35.09	35	1,563	$ 1,228.15	$ 54,845.67
87529	$ 35.09	251	4,462	$ 8,807.59	$ 156,571.58
87563	$ 35.09	31	1,084	$ 1,087.79	$ 38,037.56
87581	$ 35.09	599	6,221	$ 21,018.91	$ 218,294.89
87591	$ 35.09	1,224	98,520	$ 42,950.16	$ 3,457,066.80
87633	$ 416.78	965	7,222	$ 402,192.70	$ 3,009,985.16
87634	$ 70.20	119	1,791	$ 8,353.80	$ 125,728.20
87640	$ 35.09	2,343	5,239	$ 82,215.87	$ 183,836.51
87641	$ 35.09	3,571	4,428	$ 125,306.39	$ 155,378.52
87651	$ 35.09	439	15,049	$ 15,404.51	$ 528,069.41
87653	$ 35.09	260	2,993	$ 9,123.40	$ 105,024.37
87661	$ 35.09	202	20,083	$ 7,088.18	$ 704,712.47
87798	$ 35.09	2,691	24,194	$ 94,427.19	$ 848,967.46
87801	$ 70.20	202	4,466	$ 14,180.40	$ 313,513.20
TOTAL		**16,217**	**297,252**	**$ 1,013,493.97**	**$ 14,030,555.67**

Table 2: Total lost revenue by CPT code for Medicare claims using 2021 MarketScan data

Table 3

CPT Code	% of labs not paid by Medicare	% of labs not paid by Commercial
87481	6.5%	0.9%
87486	35.4%	9.8%
87491	16.7%	5.6%
87498	9.4%	4.7%
87502	30.5%	7.9%
87511	7.5%	4.8%
87529	15.2%	8.4%
87563	2.0%	3.1%
87581	27.7%	9.5%
87591	17.7%	6.7%
87633	56.1%	14.3%
87634	26.7%	6.1%
87640	24.1%	10.2%
87641	37.0%	9.3%
87651	9.9%	4.7%
87653	4.7%	3.9%
87661	6.4%	4.4%
87798	18.8%	7.1%
87801	5.3%	4.4%
TOTAL	19.1%	6.0%

Table 3: % of labs not paid by Medicare and Commercial payers by CPT code using 2021 MarketScan data

Table 4

2021 TOTAL LOST REVENUE		
	MEDICARE	**COMMERCIAL**
Total Lost Revenue per 2021 Fee Schedule	$ 1,013,493.97	$ 14,030,555.67
Total potential reimbursed with CMS Fee Schedule	$ 2,980,317.40	$191,664,092.25
% of Lost Revenue Compared to Total Possible Reimbursed	25.4%	6.8%

Table 4: % of lost revenue for Medicare and Commercial claims using 2021 MarketScan data

Table 5

CPT Code	MEDIAN MEDICARE	MEDIAN COMMERCIAL	CMS FEE SCHEDULE 2021	Medicare to Commercial Difference	Medicare to Fee Schedule Difference	Commercial to Fee Schedule Difference
87481	35.09	28.23	35.09	(6.86)	0	6.86
87486	35.09	28.66	35.09	(6.43)	0	6.43
87491	29.83	30.59	35.09	0.76	5.26	4.50
87498	29.83	21.05	35.09	(8.78)	5.26	14.04
87502	95.80	86.94	95.80	(8.86)	0	8.86
87511	35.09	29.24	35.09	(5.85)	0	5.85
87529	35.09	46.65	35.09	11.56	0	(11.56)
87563	35.09	24.56	35.09	(10.53)	0	10.53
87581	35.09	26.32	35.09	(8.77)	0	8.77
87591	29.83	30.59	35.09	0.76	5.26	4.50
87633	416.78	283.06	416.78	(133.72)	0	133.72
87634	70.20	52.65	70.20	(17.55)	0	17.55
87640	35.09	26.32	35.09	(8.77)	0	8.77
87641	35.09	41.33	35.09	6.24	0	(6.24)
87651	35.08	35.90	35.09	0.82	0.01	(0.81)
87653	35.09	31.58	35.09	(3.51)	0	3.51
87661	29.83	28.88	35.09	(0.95)	5.26	6.21
87798	35.09	34.66	35.09	(0.43)	0	0.43
87801	140.40	56.16	70.20	(84.24)	(70.20)	14.04

Table 5: Median Reimbursement (in 2021 U.S Dollars) by CPT code for Medicare and Commercial claims using 2021 MarketScan data, compared to the 2021 CMS fee schedule

Table 6

The SAS System

The MEANS Procedure

Analysis Variable : PAY Payment							
Lab	N Obs	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	N
87481	6321	62.28	77.50	35.09	29.83	105.27	6321
87486	1084	41.83	50.77	35.09	28.07	35.09	1084
87491	5739	35.64	45.96	29.83	28.07	35.09	5739
87498	375	29.96	19.86	29.83	18.60	35.09	375
87502	2432	95.60	44.87	95.80	82.68	95.80	2432
87511	430	34.20	7.16	35.09	35.09	35.09	430
87529	1396	45.37	37.10	35.09	28.07	59.65	1396
87563	1512	33.46	5.19	35.09	35.09	35.09	1512
87581	1560	38.37	41.61	35.09	24.56	35.09	1560
87591	5689	33.19	23.27	29.83	28.07	35.09	5689
87633	754	442.67	291.14	416.78	333.43	416.78	754
87634	327	66.36	19.60	70.20	56.33	70.20	327
87640	7394	47.75	1082.71	35.09	33.50	35.09	7394
87641	6090	42.56	38.98	35.09	28.07	35.09	6090
87651	3992	35.33	19.52	35.09	35.09	35.09	3992
87653	5214	33.52	7.16	35.09	35.09	35.09	5214
87661	2964	30.46	17.51	29.83	28.07	35.09	2964
87798	11632	169.74	186.43	35.09	35.09	387.74	11632
87801	3645	140.82	67.09	140.40	70.20	210.60	3645

Table 6: Medicare reimbursement statistics using 2021 MarketScan data

Table 7

The SAS System

The MEANS Procedure

Analysis Variable : PAY Payment							
Lab	N Obs	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	N
87481	149951	40.72	42.18	28.23	23.00	42.68	149951
87486	53799	48.64	121.40	28.66	18.94	43.70	53799
87491	1395150	47.80	54.27	30.59	25.50	48.96	1395150
87498	7350	34.09	49.04	21.05	18.94	29.51	7350
87502	119826	106.55	81.20	86.94	56.11	130.58	119826
87511	30860	36.30	22.01	29.24	19.88	51.86	30860
87529	48901	66.47	84.60	46.65	26.48	72.36	48901
87563	34101	28.86	27.69	24.56	18.60	31.58	34101
87581	59536	44.10	57.41	26.32	18.94	42.11	59536
87591	1373019	44.51	41.50	30.59	25.14	47.90	1373019
87633	43191	429.93	460.47	283.06	185.17	515.33	43191
87634	27647	72.45	53.61	52.65	42.89	82.00	27647
87640	46192	38.89	327.84	26.32	18.94	41.40	46192
87641	43245	69.01	139.85	41.33	21.44	89.79	43245
87651	303447	47.93	48.04	35.90	26.00	54.37	303447
87653	73807	43.94	39.90	31.58	21.44	49.02	73807
87661	433637	36.53	34.78	28.88	23.21	38.29	433637
87798	317468	69.95	119.47	34.66	23.01	61.28	317468
87801	98052	75.46	80.30	56.16	43.59	77.99	98052

Table 7: Commercial reimbursement statistics using 2021 MarketScan data

Figure 1 Medicare Enrollment Numbers

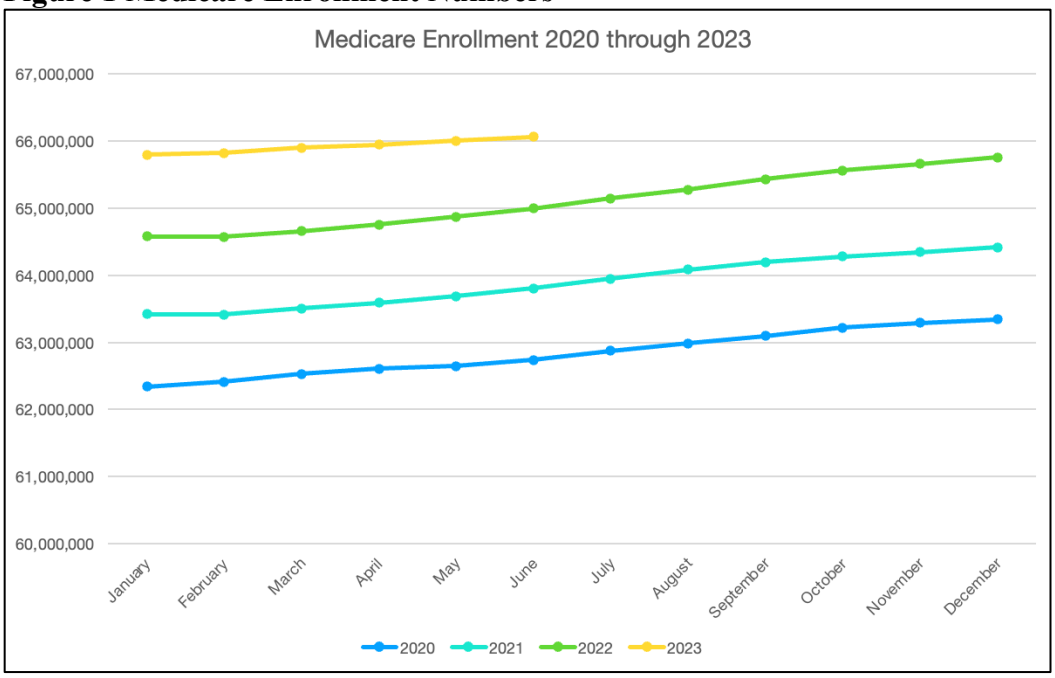

Figure 1: Comparison of Medicare Enrollment patients from January 2020 through June 2023

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%22%3A%22NOT_CONTAINS%22%7D%2C%22filterValue%22%3A%5B%22year%22%5D%7D%5D%7D%5D%2C%22rootConjunction%22%3A%7B%22value%22%3A%22AND%22%7D%7D%2C%22keywords%22%3A%22%22%2C%22offset%22%3A0%2C%22limit%22%3A10%2C%22sort%22%3A%7B%22sortBy%22%3Anull%2C%22sortOrder%22%3Anull%7D%2C%22columns%22%3A%5B%5D%7D

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